NOTE

This Microfiche meets the quality requirements of the American National Standard for Microfiche of Documents (ANSI PH5.9-1975). However, because of imperfections in the document from which it was made, it contains images that are illegible or difficult to read. The source document for this microfiche is the best copy that could be obtained prior to filming.

CIS Congressional Information Service Washington D.C.

Calendar No. 642

101ST CONGRESS
2d Session

SENATE

REPORT
101-335

FISH SAFETY ACT OF 1990

JUNE 22 (legislative day, JUNE 11), 1990.—Ordered to be printed

Mr. LEAHY, from the Committee on Agriculture, Nutrition, and Forestry, submitted the following

REPORT

[To accompany S. 1245]

The Committee on Agriculture, Nutrition, and Forestry, to which was referred the bill (S. 1245) to expand the inspection by the Secretary of Agriculture of the Nation's food supply to ensure the safety and wholesomeness of the Nation's supply of fish, shellfish and other marine food, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

CONTENTS

	Page
Introduction	2
Basis and Purpose of Legislation	3
Call to action	5
New Federal partnerships	5
Conclusion	8
Importance of the Fish Industry	8
Imports	9
Exports	9
Addressing Public Health Concerns	9
Inspecting facilities and operations	9
Testing samples and setting tolerances	10
Indicators	11
Water Pollution and the Fish Industry	12
Increased Consumption of Fish for Health Reasons	13
Consumer Fraud	14
Explanation of Certain Provisions	14
At-sea inspections	14
The Federal seal	16
Labels	16
Adulteration definition	16

39-010

S163-2

Explanation of Certain Provisions—Continued Page
Federal-State programs 17
Trade disputes 17
Sashimi and sushi 17
Subpopulations 18
Economic fraud 18
Inert chemicals 18
Consumer education 18
Recreational fishing 19
Applications of establishments and importers 19
Traceback procedures 19
Sanitary conditions 19
Recalls 20
Shellfish indicator research program 20
Foreign inspection programs 20
Industrial products 21
Implementation 21
Addendum:
Toxins of Microbial Origin 21
Scombroid fish (Histamine) poisoning 21
Ciguatera poisoning 22
Paralytic shellfish poisoning 23
Neurotoxic shellfish poisoning 24
Bacterial Pathogens of Marine Origin 24
Vibrio vulnificus 24
Viral Disease Transmission by Seafood 25
Committee consideration 26
Section-by-section analysis 31
CBO cost estimate 43
Regulatory impact evaluation 44
Changes in existing law 45
Appendices 83

Introduction

The annual consumption of seafood in the United States is almost 4 billion pounds—a consumption increase from 1980 of 20 percent. American consumers spent $28.3 billion on fish and shellfish in 1989.[1]

The United States is the world's largest exporter of seafood and the world's second largest importer of seafood. It is surprising that in spite of its huge fish and seafood industry, "[t]he United States is virtually alone among industrialized fishing nations in that it does not have a specific, systematic, mandatory seafood inspection program, but rather a general compliance program."[2]

All other flesh food, except fish, in the United States is subject to comprehensive mandatory inspection programs operated by the Department of Agriculture. Representatives of the fish industry came to the Agriculture Committee and requested legislation to address this issue. They asked that the Agriculture Department administer a comprehensive mandatory inspection program specifically designed for the fish industry.

---

[1] Most of the information concerning the U.S. fish and seafood industry is from the report "Fisheries of the United States, 1989," published by the U.S. Department of Commerce, May 1990.

[2] The quote is from an interim report on the "Model Seafood Surveillance Project" as requested by Congress. In 1986 Congress directed the Department of Commerce, the Department of Agriculture and the Food and Drug Administration to design a new inspection program for fish. This project, called the "Model Seafood Surveillance Project," will be completed this December. The interim report of this project will be cited as the "Report" in this Committee report. (There were several meetings of the Department of Commerce, Department of Agriculture and the FDA regarding this congressional mandate. The Report notes that USDA "meat and poultry inspection programs are specific, systematic, and mandatory.")

The National Fisheries Institute, by far the largest fish industry trade association, representing over 1,000 corporate members and over 40 trade association members, asked that the Department of Agriculture administer such a fish inspection program.[3]

Administration by the Agriculture Department makes sense. The Agriculture Department already inspects all other meats. Including fish in its inspection program means that the fish industry is on the same level playing field with red meat, pork and poultry. Inspection policies, regulatory practices, label approval, enforcement actions, import regulation, and other activities related to meats would be established by the same Department.

Also, the Secretary of Agriculture has the lead responsibility for negotiating GATT trade issues regarding agricultural products, including fish, and food safety matters. Harmonization of food safety trade issues by the Secretary of Agriculture is extremely important to the fish industry.

This report details the rationale for USDA administration of a comprehensive fish inspection program in the "New Federal Partnerships" section.

Basis and Purpose of Legislation

The Report[4] concluded that the current inspection program[5] is wrongly conceived and inadequate. The Report noted that the current fish inspection "patchwork" of seafood safety programs permit such levels of unsafe and unwholesome seafood:

> that [the problems] cannot be ignored and . . . cannot be even addressed, *let alone corrected, by the present patchwork system of inspection, quasi-inspection, inadequate resources,* and overlapping jurisdictions. [Emphasis added.]

The Report concludes:

> The simple fact is that at this moment inspection of seafood in this country is in great need of improvement . . . .
>
> First, unlike other major food commodities, seafood control relies heavily on a patchwork of agencies and outdated legislation, each with its own set of priorities and each with its own limited resources.
>
> Second, there is lack of uniformity in the application of regulations, due in large part to the multiplicity of jurisdictions involved with seafood systems. Further, compliance with regulations is poorly enforced.
>
> Third, there is no appropriate infrastructure to support and promote an efficient surveillance program tailored specifically for seafood.

---

[3] In addition to the National Fisheries Institute, several other regional and local fish and shellfish trade associations support the USDA inspection role. For example, the Marine Sardine Council, Maine Fisherman's Association, Shellfish Institute of North America, Virginia Seafood Council, and Catfish Farmers of America among others consider the USDA the best agency to administer a mandatory comprehensive fish inspection program.

[4] *See* footnote 2.

[5] The Food and Drug Administration takes and tests samples of some fish products along with samples of other foods. Also the National Marine Fisheries Service operates a voluntary, fee-for-service, program for the inspection and grading of some fish products.

Fish pose a wide array of potential health problems due to pathogenic bacteria and viruses, natural toxins, chemical contaminants, parasites, decomposition and drug residues. (Report at pp. 2, 7, 8, 10, and 12.) The practice of eating some fish raw also poses potential risks. Moreover, fish are highly perishable and can become contaminated during handling and processing.

Seafood is the only meat or flesh food not subject to a mandatory and comprehensive national inspection program. The lack of a comprehensive Federal inspection program creates an unfair competitive advantage for competing products. At the same time seafood may suffer from lower consumer confidence because of the lack of an adequate inspection program.

Data compiled by the Centers for Disease Control (CDC) show reported acute onset illnesses from fish are mainly from pathogens in raw molluscan shellfish and from ciguatera and scombroid poisoning. The consumption of raw molluscan shellfish, in particular, is associated with a high rate of illness on a pound for pound basis.[6]

Over 20 percent of the disease outbreaks (illnesses affecting 3 or more persons from the same food or other source) reported to CDC, in the last 15 years, were attributable to fishery products. Annual economic losses caused by illnesses and death from just three types of seafood toxins are estimated to be in excess of $125 million.[7]

Chemical contaminants in fish and shellfish are of growing concern to the public. An Environmental Protection Agency (EPA) report notes that, "[c]ontamination of aquatic resources by toxic chemicals is a well recognized problem in many parts of the U.S." [8]

The EPA Report further notes:

> High concentrations of potentially toxic chemicals have been found in sediments and in aquatic organisms from [many parts of the United States] . . . . Heavy consumption of contaminated fisheries products by humans may pose a substantial health risk.

There is a growing negative perception in consumers' minds about the safety of fish. News reports of ocean pollution and chemical runoff into lakes and rivers are contributing to lowered public confidence. As evidenced in the case of Alar in apples, public concern about possible contamination of food can quickly escalate. It is important to public health and to the fish industry that the toxic chemical problems regarding growing and harvesting waters be addressed by Federal, State and local governments.

With increased consumption of fish, there is pressure to harvest fish of marginal quality, or from waters of less than adequate quality. "Bootlegging" of shellfish from contaminated areas is a continuing problem, further aggravating public health concerns. Also

---

[6] *See* testimony of Prof. Michael Dicks, Oklahoma State University, before the House Subcommittee on Department Operations, Research, and Foreign Agriculture, February 7, 1990.

[7] "Preliminary Estimates of Costs of Foodborne Disease in the United States," Ewen Todd, vol. 52, *Journal of Food Protection* (1988). *Also see*, testimony of Prof. Michael Dicks, Oklahoma State University, presented before the House Agriculture Subcommittee on Department Operations, Research, and Foreign Agriculture, February, 7, 1990.

[8] EPA has recently issued a useful guidance manual entitled: "Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish: A Guidance Manual." The report was issued in September 1989 (EPA–503/8–89–002). That report is referred to as "EPA Report" in this Committee report.

the trend to transport fish over longer distances with more points along the distribution chain increases the potential for abuse. Yet, fish and shellfish are the only flesh foods of any significance not subject to a comprehensive, mandatory Federal inspection program.

CALL TO ACTION

The Report and the National Research Council (NRC), National Academy of Sciences, call for major changes in the way we inspect seafood. Those ideas are incorporated in S. 1245, the "Fish Safety Act of 1990."

The Report calls for a "single Federal regulatory agency [with] operational authority to monitor and enforce the system . . . ." The Report explains that the program should be mandatory, should sample products, inspect facilities, and apply to imports from foreign suppliers. Under the bill USDA would be the single federal regulatory agency to monitor and enforce the system—both for imports and for domestic production. Separating these important functions would make proper program administration very difficult.

The NRC noted that food safety microbiological control programs should have three basic elements: "education and training, inspection of facilities and operations, and microbiological testing" (NAS, 50).[9]

The food safety aspects of the reported bill address these elements. The bill provides funding for education and training, sets up a national system of testing fish products for harmful contaminants, creates a mandatory national system of inspecting facilities and operations, and establishes inspection programs for foreign nations that export to the United States. Also, grant money would be available to assist states in developing inspection programs based on federal guidelines.

In addition, the EPA Report clearly shows how important it is to the fish industry, and to those who consume fish, that pollution problems in our oceans, rivers, lakes and streams be addressed. Cleaning up our Nation's growing and harvesting waters would greatly improve the quality and wholesomeness of fish products.

NEW FEDERAL PARTNERSHIPS

The bill divides responsibility for the program to take advantage of the existing expertise and resources of three Federal agencies: the Food Safety and Inspection Service (FSIS) of the Department of Agriculture, the Food and Drug Administration (FDA) of the Department of Health and Human Services, and the National Marine Fisheries Service of the Department of Commerce.[10]

The Food and Drug Administration (FDA) would continue to set the tolerances which form the basis for the inspection system. A

---

[9] The reference to NAS refer to the National Academy of Sciences major report: *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*, National Academy Press (1985).

[10] In addition, under the bill the Environmental Protection Agency would continue its important role under the Federal Food, Drug and Cosmetic Act to establish tolerances levels (maximum permissible concentrations) or action levels for pesticides in raw agricultural commodities including fish and shellfish.

major current responsibility for FDA is setting tolerances for foods, including fish, under the Federal Food, Drug and Cosmetic Act.[11]

While only one tolerance (polychlorinated biphenyls) and 16 informal "action levels" (methyl mercury, paralytic shellfish toxin, histamine in canned tuna and 13 pesticides) have been set for fish,[12] the bill contemplates that FDA (or EPA in certain circumstances regarding harmful chemicals) would set tolerances for harmful chemicals, toxins, parasites, pathogenic microorganisms, viruses, bacteria, and other harmful agents, that may render fish products adulterated.

The Federal Food Drug and Cosmetic Act provides general authority for the FDA to inspect food. While this authority applies to fish and seafood, it is inadequate to implement a modern program of inspection. The FDA, for example, does not have authority to deny entry of imported products on the basis that the exporting country has an inadequate inspection and testing program, nor does it have adequate authority to review records or detain domestic products.

The FDA employs under 2,000 inspectors in the field who are shifted from one food or drug sector to another. These inspectors cover all food products, except meat and poultry, and some 67,000 food-related facilities. A GAO report noted that,"[in] fiscal year 1988, FDA allocated its district offices a total of 150 staff years for domestic food safety program activities." [13] As a general rule these food-related facilities are not registered with FDA and are inspected very infrequently.

As part of its general food program the FDA samples about 1 percent of domestic fish products and 3 percent of fish imports each year. It also administers two specific programs, the National Shellfish Sanitation Program which is a cooperative effort with the States and industry, and the salmon control plan, where inspectors from the National Food Processors Association and the FDA monitor domestic salmon processing.

This bill provides that the U.S. Department of Agriculture be given lead responsibility for inspecting and testing fish products. USDA already performs this role for all other flesh foods. Unlike the general food program of the FDA, the Food Safety and Inspection Service (FSIS), USDA, carries out inspection programs specifically designed for meat.

USDA has over 100,000 employees (with a budget of $48 billion) with over 9,000 employees in FSIS. In contrast FDA has 7,200 employees total (and a budget of about $500 million) in FY 1989.

With its massive physical presence in the United States and throughout the world, USDA would carry out the sampling, inspection and enforcement functions. FSIS employees now inspect about

---

[11] The jurisdiction of FDA and EPA is summarized in "EPA/FDA Summary Policy Statement of Chemical Residues in Fish and Shellfish" found in appendix A of the EPA Report.

[12] Testimony of James Benson, Acting Deputy Commissioner of the food and Drug Administration, before the House Subcommittee on Department Operations, Research, and Foreign Agriculture, February 7, 1990.

[13] GAO Report HRD–89–125.

150 billion pounds of meat products. USDA offices nationwide [14] and worldwide could be used to support additional inspectors.

FSIS has a supervisory network of 5 regional offices, 26 area offices, and 200 inspection circuits and employs over 7,000 inspectors, 1,200 veterinary medical officers, and support staff. FSIS has 3 state-of-the-art in-house laboratories (Georgia, California and Missouri), 2 contract laboratories, and 315 accredited private laboratories to analyze meat for chemical and drug residues, microbiological problems, processed product composition and economic adulteration.[15]

GAO recently noted that FDA estimated it needs 2,000 additional positions—more than a 25 percent increase in staff—just to administer its current programs.[16] FDA presently needs to strengthen its activities in other areas by "streamlining" FDA's role in the overall Federal fish inspection program. Moreover, FDA's enforcement functions regarding imported foods have been subject to scathing criticism. "Hard to Swallow: FDA Enforcement Program for Imported Food," Committee Print 101-L, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce (July 1989).

USDA fish inspection personnel in many instances will be able to share existing USDA office space, and share existing USDA support staff, food safety equipment, word processors, computers, telephone systems, and other items. USDA also has an extensive management staff already in the field—throughout the United States and the world. The Committee directs USDA to locate fish inspection offices in geographic locations that will facilitate fast and ready inspection for the fishing industry.

USDA inspects foreign plant operations regarding the quality of meat and poultry imports. USDA inspectors routinely visit foreign plants producing meat and poultry for export to the United States. In addition, there is a national network of FSIS inspectors that reinspect imported meats and poultry at ports of entry for compliance with domestic standards.[17] This is the only import food inspection system in place that is capable of handling the volume of fish products imported into the United States.

The third Federal agency, the Department of Commerce, would continue its role managing fisheries in offshore waters. The Department administers and enforces laws which govern some of the richest fisheries in the world. With the new 200 mile exclusive fishing zones that Department has a massive responsibility. This bill recognizes the important role of the Commerce Department, par-

---

[14] Just two agencies of USDA have almost 5,000 offices. The Agricultural Stabilization and Conservation Service of USDA, for example, has 3,000 offices, and the Farmers Home Administration has 1,950 offices and 250 district offices. In contrast, FDA has 21 district offices. The USDA statistics are from a USDA budget summary for FY 1991 (regarding 1989 and 1990 staffing and budget levels). The FDA data is from GAO report HRD-89-142 (September 1989).

[15] Most of the FSIS information is from a FSIS report to Congress, "Meat and Poultry Inspection, 1989," Assistant Secretary of Agriculture Jo Ann Smith testified before the Senate Agriculture Committee on October 24, 1989, that during fiscal year 1988, the FSIS laboratories completed over 2.1 million analyses on nearly 500,000 statistically selected samples of meat.

In contrast FDA tested only about 2,000 domestic seafood samples and conducted only between 10,000 and 20,000 individual analyses. (Testimony of Commissioner Frank Young, October 24, 1989, before the Senate Agriculture Committee.)

[16] FDA is currently very understaffed (GAO report HRD-89-142, September 1989).

[17] In 1988 this national network of FSIS personnel reinspected 2.8 billion pounds of flesh foods from 40 countries.

ticularly in regard to classification of fish harvesting areas and the regulation of vessels.[18]

CONCLUSION

The legislation is designed to protect public health, assist the fish industry, help States wishing to improve water and fish product quality, and reduce the possibility of economic fraud. It draws on the resources, the infrastructure, and the expertise of four Federal agencies to assure the wholesomeness of fish products for human consumption.

The legislation is also designed to improve public confidence in the safety and wholesomeness of fish products, by both making the products more wholesome and by training and educating persons in the proper handling and preparation of fish.

The legislation, at the request of a major segment of the fish and shellfish industry, puts the monitoring, inspection and enforcement functions in the Department of Agriculture. USDA would then administer inspection, label approval, sampling, and testing programs for all meats.

IMPORTANCE OF THE FISH INDUSTRY

The United States is a major fishing nation ranking behind only Japan, the Soviet Union, China and Peru. U.S. fisherman harvested 8.5 billion pounds of fish in 1989 including more than 300 species of fish and shellfish. U.S aquaculture operations on farms produced an additional 400 million pounds. This production passed through over 4,200 processing and wholesale facilities before reaching consumers.[19]

The seafood industry is large and diverse. It attracts independent people who are self-sufficient and often self-employed. It is also a highly seasonal industry with varying production levels from year to year. More than 270,000 persons are employed on harvesting (fishing) vessels and more than 100,000 work in shore-side facilities.

The United States and Canada together have the world's largest fishing grounds on their continental shelves. The domestic catch is harvested by over 130,000 fishing vessels and is processed in around 2,000 processing plants. Some 60 U.S. ports land more than 10 million pounds annually.

A rapidly growing fleet of U.S. vessels now includes over 50 factory vessels which process fish at sea into fish mince or fillets which are packaged and frozen onboard. These vessels, valued at between $15 million to $35 million each, remain at sea for months at a time. Fish tender vessels take products off processing and harvesting vessels and transport them to other vessels and shore-based facilities.

Per capita consumption of fish was almost 16 pounds in 1989 (edible weight), compared to about 68 pounds of chicken (retail

---

[18] Note that States routinely monitor water quality and conduct chemical analyses of fish and shellfish tissue as part of their environmental monitoring activities. The Clean Water Act requires States to develop lists of "impaired waters, identify point source discharges of toxic substances and amounts of pollutants present, and develop individual control strategies (permits) for each point source discharger." EPA Report, pp. 6 and 7.

[19] *See* footnote 1.

weight) and 69 pounds of beef (retail weight), according to the USDA's Economic Research Service.

Nearly 75 percent of U.S. commercial landing can be accounted for by six product categories—shrimp, crabs, pollock, salmon, herring and flounder.[20] Shrimp and crabs account for nearly 65 percent (786 million pounds) of all shellfish. The remaining 35 percent is accounted for by clams (132 million pounds), squid (127 million pounds), lobster (576 million pounds), scallops (44 million pounds), and oysters (32 million pounds).

IMPORTS

The United States imports seafood from 125 countries—in 1989 3.2 billion pounds of edible fish worth $5.5 billion were imported. Over 60 percent of all seafood consumed in the United States is imported.

Major frozen imports include finfish, primarily from Canada and northern Europe, and shrimp, much of which is being supplied by foreign aquaculture operations, especially from Ecuador (103 million pounds in 1988), China (104 million pounds in 1988) and other Asian countries. Canned products, particularly canned tuna, also is a major import item. Canned or cured product represent nearly one-third of all imports. The balance is fresh or frozen product.

More than 30 percent of all imports are composed of tuna products—500 million pounds of whole or eviscerated tuna and 250 million pounds of canned tuna. Shrimp is the fastest growing import accounting for over 15 percent of the total volume of imports.[21]

EXPORTS

The United States is the world's largest exporter of seafood, with Japan purchasing over half the exports. The total export value of fishery products of domestic origin was $4.7 billion in 1989—an increase of $2.4 billion over 1988.

Addressing Public Health Concerns

INSPECTING FACILITIES AND OPERATIONS

Much of the evidence presented to the Committee favored the creation of a fish inspection program based on the "Hazard Analysis Critical Control Point"[22] system often referred to as HACCP.

---

[20] References to testimony refer to testimony provided at hearings before either House or Senate subcommittees or committees during this Congress. The references in this text are keyed to this list of hearing dates:

June 5, 1989, Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce;

June 6, 1989, Senate Committee on Labor and Human Resources;

October 24, 1989, Senate Committee on Agriculture, Nutrition, and Forestry;

November 9, 1989, Subcommittee on Fisheries and Wildlife Conservation and the Environment of the House Merchant Marine and Fisheries Committee;

February 7, 1990, Subcommittee on Department Operations, Research, and Foreign Agriculture of the House Committee on Agriculture;

April 25, 1990, Subcommittee on Fisheries and Wildlife Conservation and the Environment of the House Merchant Marine and Fisheries Committee; and

May 24, 1990, Senate Committee on Commerce, Science, and Transportation.

This reference is to the testimony of Prof. Michael Dicks, February 7, 1990.

[21] The facts on imports and exports were either taken from "Fisheries of the United States: 1989" or from the testimony of Prof. Michael Dicks, February 7, 1990.

[22] The bill sets up a HACCP system under section 1903(c), of title XIX, especially subparagraphs 2 through 6 and subparagraph 10.

HACCP can be used to monitor the quality of products without examining each and every product prior to its use.

The National Research Council (NRC) put it bluntly: "[t]he safety and quality of fish and fishery products can best be assured by application of the HACCP system" (NAS, 253). It is a cost-efficient method of assuring predictable outcomes which has been used by industry for several decades. For example, HACCP has been used in monitoring the safety of low-acid canned foods in the United States since 1973 (NAS, 308).

With respect to food quality assurance procedures the NRC has defined HACCP as a system which consists of:

(1) identification and assessment of hazards associated with growing,[23] harvesting, processing, marketing, preparation, and use of a given raw material or food product;

(2) determination of critical control points to control any identifiable hazard; and

(3) establishment of systems to monitor critical control points (NAS, 2, 51).

NRC stated that properly applied the HACCP system separates the essential from the superfluous aspects of microbiological control. This leads to "more effective and economical utilization of regulatory manpower" (NAS, 51).

There is no question, as the NRC points out that "the quality of raw fish can best be assured through application of the HACCP approach by sensory inspection of raw materials, proper temperature control, sanitation of equipment, and proper handling of product by employees" (NAS, 7). The NRC further notes that "in the application of HACCP the use of microbiological criteria is at times the most effective means of monitoring critical control points." They further point out that HACCP's food safety debut, regarding the low-acid canned products industry, was a success in part because the use of HACCP was mandated by Federal law (NAS, 309).

As mentioned in footnote 2, in 1986 Congress directed the Department of Commerce, Department of Agriculture and the Food and Drug Administration to design a new inspection program for fish based on the HACCP system. This work, called the "Model Seafood Surveillance Project," will be completed at the end of this year. The interim Report recommends that a HACCP program be implemented for fish over the next 3 years which would require plant registration and inspection, the sampling and testing of products, equal treatment of domestic and imported products, public education and research. All these elements are incorporated in the Committee reported bill.

TESTING SAMPLES AND SETTING TOLERANCES

The U.S. Department of Agriculture (USDA) administers a nationwide system for taking samples of flesh foods (red meats, pork flesh, poultry, and other meats) both at slaughtering establishments and from import shipments at ports of entry. The system is called the "National Residue Program" (NRP) and is described in

---

[23] The Environmental Protection Agency (EPA) has issued an exhaustive analysis of the issue of risk assessment regarding seafood: *Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish: A Guidance Manual*, 1989.

detail in the USDA publication the "Compound Evaluation and Analytical Capability, National Residue Program Plan: 1989" (referred to as NRP report in this report).

USDA planned on analyzing over 95,000 "sample units" in 1989 for pesticide chemicals, environmental contaminants, trace metals, industrial chemicals, animal drugs, and "other potentially hazardous chemicals that may contaminate meat and poultry." (NRP report, preface and p. 5.2.)

The USDA program takes into account a number of factors such as: the potential adverse health effects of the hazard (adverse affects that may be produced by a given chemical); likely exposure levels (residue concentration and other factors affecting concentrations of chemical including use patterns); longevity of the chemical and its metabolites; and other factors which could adversely affect "public health." (NRP report, 1.A, or degradation products pp. 2-4.)

In determining which samples to take the Department uses statistical models for random sampling and also targets sample taking for known problems. This dual approach is also suitable for the sampling and testing of fish products under this bill.

The bill requires that the Food and Drug Administration (or the EPA in certain cases) continue to establish tolerances for harmful chemicals, toxins, parasites, pathogenic microorganisms, viruses, bacteria, and other harmful agents, that may render fish products adulterated.

In 1985 the NRC pointed out several pathogens, among others, which they felt needed careful monitoring regarding fish:

Viruses from human sewage causing hepatitis A and other illnesses, especially from raw or inadequately cooked shellfish that are harvested from sewage-polluted waters (NAS, 82);

Vibrio cholerae bacteria (and other vibrio bacteria species such as *V. mimicus, V. fluvialis, V. vulnificus,* and *V. hollisae*) especially regarding raw or undercooked oysters, mussels and clams (NAS, 18, 34, 80);

Saxitoxin and other toxins which cause paralytic shellfish poisoning from consumption of mussels, clams, soft-shelled clams, butter clams and scallops (NAS, 19, 84);

Ciguatera toxin, especially in fish which feed on certain dinoflagellates typically around tropical reefs (NAS, 19); and

Histamine, or scombroid, poisoning regarding scombroid fish such as tuna, mackerel, bluefish and mahi-mahi (NAS, 21, 119).

The National Research Council noted that tolerances for specified microbiological contaminants would be useful. They point out that (1) the pathogen or toxin of concern should be specified; (2) the analytical method to determine the presence of the contaminant should be announced; (3) the plans for taking samples of product should be developed; and (4) the level of population of a pathogen or concentration of toxin that must not be exceeded (the tolerance level) should be specified (NAS, 52, 55, 56).

INDICATORS

In many circumstances it would be much more cost-effective to set a tolerance for a substance that would normally indicate the presence of the harmful contaminant rather than setting the toler-

ance for the harmful contaminant itself. These circumstances arise when the tests for determining the presence of the harmful contaminant are more difficult, more costly, or less reliable than the tests determining the presence of the indicator.

These substances are often referred to as "indicators" because their presence correlates highly with the presence of some other substance which is more costly or difficult to detect. The bill provides for the use of these indicators in the setting of tolerances by the Food and Drug Administration.

The Committee notes that in the NAS study that several indicators of harmful substances in fish are described. For example, ethanol can be used as an indicator of the microbial decomposition of canned salmon (NAS, 24, 118). E. coli, Staphylococcus aureus, fecal coliforms and other coliforms can be used as indicators of several harmful contaminants and microbiological organisms in certain species of fish (NAS 25, 122, 123, 124, 125).

A witness testified that:

> A seafood product produced under a HACCP system that has very low levels of Staphylococcus aureus and coliforms [two indicators] would indicate good sanitation, good temperature control, and the likelihood of pathogens being present as being close to zero. . . . These two indicators can also show whether abuse of the product has occurred in the distribution system.[24]

Trimethylamine and total volatile nitrogen has been used for the evaluation of the quality of fish such as cod, haddock, hake, and shrimp (NAS, 116, 117).

Indole, which is formed by the action of bacteria on tryptophan in shrimp and oyster tissue, is a good indicator of the decomposition of those products (NAS, 117, 118). Measuring the pH of fish can determine the "degree of quality deterioration" (NAS, 113, 114). For example, the pH of fish and shrimp can increase during storage because of the production of ammonia and amines by microbial and tissue enzyme activity.

Water Pollution and the Fish Industry

The National Research Council notes that:

> Fish, molluscs, and crustaceans can acquire pathogenic microorganisms or toxins from the natural aquatic environment, from sewage-contaminated harvesting areas . . . during harvesting, processing, distribution, and food preparation.

Sedentary shellfish such as clams, oysters and mussels are filter feeders. As a result harmful microorganisms and pollutants are concentrated. If growing waters are polluted the shellfish can become sources of hepatitis and viral infection.

Dr. John MacMillan of the College of Veterinary Medicine, Mississippi State University, noted that some fish are known to bioac-

---

[24] Dr. Bauman, testimony of February 7, 1990.

cumulate up to 100 times ambient levels.[25] It cannot be stressed enough: cleaning up our coastal waters, bays, rivers and lakes is extremely important to the fish industry and to the wholesomeness of harvested fish products.

Fortunately, bacterial diseases of fish and shellfish are mostly caused by unique pathogens of fish and are of no concern to humans. None of the viruses causing diseases of fish or shellfish are believed to be transmissible to humans (Dr. John MacMillan's testimony).

Several papers were presented at a symposium sponsored by the Institute of Food Technologists on the microbiology of marine food products.[26] There are three broad classifications of causes of microbiological problems associated with seafood: toxins, viruses and bacteria. The Addendum to this report contains a discussion of these concerns.

The chemical pollution of our coastal areas, rivers, and lakes is well documented.[27] The pollution of our waters is having major adverse effects on the domestic fish industry. In local areas, pollution can rapidly destroy the economic viability of communities.

The bioaccumulation of toxic chemicals by fish and shellfish can exacerbate the problems of water pollution. Human health risks from consumption of chemically contaminated fish and shellfish has been thoroughly documented (EPA Report and EPA "Risk Assessment Guidelines of 1986").

Under the bill, FDA and EPA will set tolerances for potentially harmful chemical contaminants found in fish. USDA will sample and test fish products throughout the United States to assure their wholesomeness. Additionally, the bill provides for Federal funding for States to assist them in reducing the risks associated with fish consumption.

Increased Consumption for Health Reasons

At the same time that growing concern exists regarding the safety of fish, American consumers are becoming increasingly aware of the link between diet and good health, especially regarding heart disease and some forms of cancer. The *Surgeon General's Report on Nutrition and Health* (1988) recommends that the general public monitor its intake of cholesterol and saturated fats.[28]

---

[25] Testimony presented to the House Agriculture Subcommittee on Department Operations, Research, and Foreign Agriculture, February 7, 1990.

[26] Four key articles presented at that symposium were printed in the March 1988 issue of *Food Technology* which is produced by the Institute of Food Technologists. They have granted permission to reprint these articles in this report. The articles are found in appendix II. The articles are: "Factors Affecting Microbiological Quality of Seafoods," Donn R. Ward and Nina J. Baj, North Carolina State University and Texas A&M University, respectively; "Marine Toxins of Microbial Origin," Steve Taylor, University of Nebraska; "Viral Disease Transmission by Seafoods," Charles P. Gerba, University of Arizona; and "Seafood-Borne Bacterial Pathogens of Marine Origin," Cameron Hackney and Angela Dicharry, Virginia Polytechnic Institute & State University and Gulf Coast Research Laboratory, respectively.

[27] For a listing of recent references see pp. 77 through 91 of the EPA Report. The EPA Report, another EPA report ("The Risk Assessment Guidelines of 1986," EPA publication 600/8-87/045), and various State health advisories regarding fish consumption, demonstrate the serious nature of the pollution problem.

[28] Seafoods are low in cholesterol and contain long-chain polyunsaturated fatty acids of the omega-3 series which have been associated with lower incidence of heart disease. (*Surgeon General's Report on Nutrition and Health*, pp. 107-109, 163.)

Consuming seafood is a good way to reduce one's intake of cholesterol and saturated fats while consuming foods with high protein content and nutrient density.

The Surgeon General of the United States concluded that "[t]he consumption of fish and other marine animals may confer special benefits in reducing CHD [coronary heart disease] mortality" and mortality and morbidity from strokes. These characteristics increase the desirability of seafood, but also suggest the need for better control over labeling.

Consumer Fraud

The Report notes that consumers also face problems related to the mislabeling (referred to in the reported bill as "misbranding") of fish. Because there are so many different species of fish, some less expensive varieties are sold as more valuable products. That report points out that:

> Further complicating matters is the fact that there are sometimes different regional names for the same species, inviting a different kind of fraud: charging for an expensive product while actually selling a cheaper one.

The Report points out that overglazing of frozen fish, which involves placing excessive ice on the product and including the weight of the ice in the price, is another illegal practice. Additional problems are overbreading products or adding water without proper labeling.

Economic fraud can represent a public health concern, as when allergic or susceptible consumers are misled through improper labels. In other instances, consumers are cheated and honest fish processors and dealers are put at a competitive disadvantage.

Explanation of Certain Provisions

AT-SEA INSPECTIONS

The bill provides that at-sea processors (fish processing vessels) would be inspected. The Committee's decision not to require the physical inspection of harvesting vessels at this time was based on four major factors: cost-efficiency; national sampling and testing requirements; traceback procedures; and the Commerce Department's authority to close waters to commercial harvesting.

The Committee is convinced that an effective fish inspection system can be designed without incurring the additional expense of placing inspectors on every harvesting vessel. There are over 100,000 domestic harvesting vessels. Designing a system to randomly and regularly inspect these vessels would be very expensive.

Instead, the Committee believes that the funds saved by not sending inspectors on harvesting vessels will mean that much more product can be tested for harmful chemicals, pesticides, and other toxic substances.

The bill sets up a national system for taking samples of fish and subjecting them to rigorous tests for harmful substances. While an inspector on a harvesting vessel could determine that proper temperature controls were applied and that the fish was properly

stored and handled, the fish could contain unsafe levels of contaminants invisible to the eye.

Another advantage to the land-based system is that it will determine if the product, itself, is wholesome closer to actual consumption by the consumer. Since such systems are more cost-effective USDA can look at, perhaps, several times more samples with any given level of appropriated funding.

Sampling the product onshore can help pinpoint that nature of any problems on harvesting vessels. For example, Dr. Howard E. Bauman, Ph.D., in testimony provided on February 7, 1990, made it clear that temperature abuse, mishandling, improper storage, or unclean equipment on harvesting vessels would show up in tests of the product. For example, if tuna is not properly chilled and was improperly handled, samples would test for histamine (temperature abuse), coliforms and Staphylococcus aureus (mishandling).

Dr. Bauman noted that:

> A seafood product . . . that has very low levels of Staphylococcus aureus and coliforms would indicate good sanitation, good temperature control and the likelihood of pathogens being present as being close to zero. These two indicators can also show whether abuse of the product has occurred in the distribution system.

In addition to the national sampling and testing system, the bill requires that the Secretary report "any significant instance or trend in the condition of fish products that may pose a significant threat to the health and safety of consumers." The Secretary also must establish procedures, including the marking of containers or packages, or lot processing or recordkeeping, to assist the Secretary in determining sources of contamination, including determining which harvesting or growing areas are likely to produce fish that are adulterated.

The recordkeeping provisions require that fish processors (establishments) maintain records on the delivery, sale, movement, or disposition of fish products. Thus, if the national sampling and testing system turns up problems, the Secretary must notify the appropriate State or Federal agencies. Also, notification is to be published in the Federal Register.

Finally, the Department of Commerce may use this information to determine whether harvesting areas should be closed or restricted to commercial harvesting.

The bill requires a study of the usefulness of making harvesting vessels subject to random inspection. In this regard it should be pointed out that proper temperature and sanitary controls onboard would prevent many types of problems from occurring.

The bill does provide for the inspection, at-sea, of processing (factory) vessels. The Committee recognizes the difficulty of conducting frequent, unannounced inspections aboard those vessels identified in the bill as processing establishments. Some vessels are at sea for up to 60 days at a time. Some inspection duties, such as review of HACCP records and product sampling, can be performed when vessels return to port.

However, at-sea inspections of processing vessels are authorized under the bill. The Committee contemplates that inspectors board-

ing at-sea processing establishments will likely be transferred to and from Coast Guard ships on patrol. The Committee does not intend to place an inspector onboard vessels for the duration of a fishing voyage. Such an approach would not be cost-effective.

Also, that would amount to continuous inspection for a fish processing establishment. The Committee intends that there be minimal disruption of fishing or processing activities when arrangements are made to bring an inspector onboard.

THE FEDERAL SEAL

The bill permits the Secretary of Agriculture to allow fish products processed at approved establishments to bear a seal that the product is processed in accord with Federal standards.

The needs and requirements for an effective meat and poultry inspection program are different from that appropriate for a fish inspection program. The current red meat and poultry seal States that each product was inspected and passed. Red meats and poultry plants are continuously inspected. A Federal official is inspecting the products, and the plant operations, during each hour of operation.

The inspection program under this bill does not require the continuous presence of Federal inspectors. Indeed, it would be nearly impossible to inspect every single fish. It is not the Committee's intent that a continuous fish inspection program be implemented similar to that used for meat or poultry plants.

Instead, the new system is based on the "Hazard Analysis Critical Control Point" (HACCP) system which does not require a continuous presence. Under that bill inspectors may randomly inspect processors to see if the operations are consistent with the safe handling of fish products.

Inspectors will look at sanitation procedures, temperature controls, cleanliness, and whether the products are being properly handled, packaged, stored, and processed. Unlike meat and poultry, each processor will not be continuously monitored. For that reason it would be inappropriate to place a seal on fish products which implies that each product has been individually inspected.

LABELS

The bill imposes a labeling approval system based on the current system for meat and poultry. The bill will require, once the label approval system is in place, that either each type of label is preapproved by USDA or is a USDA "standard" label.

The Department should carefully phase-in this new label approval system to ensure that there is no disruption when the gradual conversion to the new system takes place. The Committee expects that the label approval system would have to be in place before prior approval of any label could be required.

ADULTERATION DEFINITION

The definition of adulteration found in the bill is very similar to that found in the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Federal Food, Drug and Cosmetic Act. The Committee anticipates that the Secretary of Agriculture will

aggressively enforce the various aspects of the definition of adulterated seafood to assure that fish products in interstate commerce are not unhealthful, unwholesome, injurious to human health, unsound, or otherwise adulterated.

Under current law, the Secretary of Agriculture is able to move quickly to act against, or otherwise seize and condemn, adulterated products. The Committee intends that the adulteration definition for fish products be enforced in the same swift manner.

FEDERAL-STATE PROGRAMS

States may operate the inspection and sampling aspects of the Federal inspection program on behalf of the Secretary. In these circumstances persons adversely affected by actions of State inspectors or officials would appeal directly to the Federal level. Since the State inspectors and officials are acting on behalf of the Secretary of Agriculture the affected persons are contesting the Secretary's program.

In light of the nature of these programs, any records or reports maintained or issued in connection with these types of Federal-State programs would be subject to the Freedom of Information Act.

TRADE DISPUTES

Provisions of the bill refer to the United States Trade Representative and the President regarding trade negotiations. Authority is provided to protect domestic interests, if necessary, in response to any unfair trade restrictions placed on United States exports of fish products by foreign countries. The Committee intends that unfair restrictions on the imports of United States fish products be swiftly and effectively resolved by our trade negotiators and by the President.

SASHIMI AND SUSHI

Section 1903(d) contains a provision stating that the program established by the Secretary shall not require the freezing or cooking of fish products that are intended for raw consumption unless the Secretary determines that such freezing or cooking is the only practical procedure available that will adequately prevent, eliminate, or control an identified source of adulteration in the specified fish species.

As indicated by the provision, the Committee intends that the required inspection program should not produce, in effect, an across-the-board prohibition on the consumption of raw fish. The Committee recognizes that some health hazards may be associated with the raw consumption of certain fish species, and that certain procedures may need to be prescribed for addressing those particular hazards, including consumer education.

The Committee concludes that a narrowly tailored procedure for addressing such hazards on a species-by-species basis may be appropriate. The Committee notes that cooking or freezing can alter the taste of fish intended for raw consumption and would necessarily change the fundamental nature of the product. The Committee concludes that freezing or cooking should only be required when a

source of adulteration of a particular species has been clearly identified and other practical remedies have been exhausted. At the present time the weight of evidence clearly suggests that freezing is not necessary for tuna.

SUBPOPULATIONS

The Committee notes that some subpopulations of Americans will consume much more than the "typical" amount of fish per year. Persons living in coastal areas, or on lakes or rivers, may fish extensively for their own consumption.

Tolerances established under this bill, if based on average consumption patterns, may not adequately protect subpopulations which consume several times more than average of particular types of fish or fish more likely to be highly contaminated. The EPA Report noted that "[h]eavy consumption of contaminated fisheries products by humans may pose a substantial health risk." Moreover, ingestion of different types of chemical contaminants may lead to additive, cumulative or synergistic effects with resultant adverse health risks. The EPA Report and "The Risk Assessment Guidelines of 1986" explain some of these concerns.

ECONOMIC FRAUD

The Committee intends that significant efforts be made to protect the public, and honest fish harvesters, wholesalers, brokers, and retailers, against economic frauds perpetrated by the few. The Department of Agriculture should devote adequate resources to the enforcement of the prohibitions against misbranding or adulteration of fish products in ways which promote economic fraud.

The bill makes it a serious crime to place false or misleading labels on fish products, or to conceal damage or an inferiority in the product. The Committee intends that the Department aggressively enforce these prohibitions so that honest fish merchants and harvesters are not at a competitive disadvantage. Deceptively labeled or packaged fish products can compete unfairly with properly labeled and packaged products. This operates to the detriment of consumers, the public and the industry.

INERT CHEMICALS

The Committee intends that tolerances for pesticides, or other chemicals, found in fish be based on how potentially harmful the chemicals are to consumers. Thus, for example, an ingredient in a pesticide which does not assist in killing the insects (inert ingredients) could be nonetheless potentially harmful to humans.

CONSUMER EDUCATION

The proper refrigeration, handling and preparation of seafood products by consumers, retail stores and restaurants would greatly assist in the reduction of foodborne illnesses associated with seafood. Consumer education programs could significantly reduce the incidence of certain types of foodborne illnesses.

The Extension Service, which is the educational arm of the Department, with agents in every county in the Nation, could greatly assist in these efforts. Under two separate sections of the bill, a

total of $2,750,000 is made available per year for these types of consumer educational efforts.

RECREATIONAL FISHING

Recreational fishing is itself a significant industry. The Report estimates that in 1988 that 17 million marine fishermen caught over 600 million pounds of finfish. It is difficult to get accurate estimates. The bill exempts recreational vessels from coverage. The Committee expects that the Department in defining the term "recreational" will consider whether the primary use of the vessel is to harvest fish for sale in interstate commerce. Vessels whose predominant use is to harvest fish for sale in interstate commerce should not be considered "recreational vessels."

APPLICATIONS OF ESTABLISHMENTS AND IMPORTERS

The Secretary should consider creating a joint application form to be used by persons who wish to apply to become both an establishment and an importer.

TRACEBACK PROCEDURES

Section 1903(d) requires that the program for inspection and sampling establish procedures to assist the Secretary in determining sources of contamination, including determining which harvesting or growing areas are likely to produce fish that are adulterated. The Committee does not intend for these procedures to be onerous.

In fact, existing lot processing or recordkeeping procedures should be sufficient in most cases to assist in traceback efforts. Traceback procedures are an important tool for identifying and correcting problems which cause fish to be adulterated. It is much better from the perspective of fish harvesters to have causes of contamination eliminated than to condemn the fish after it has been caught and put into interstate commerce. The Committee recognizes that exact traceback to vessels or harvesting areas may not be possible and that best efforts will suffice.

Indeed, the bill provides for the Secretary to financially assist States to help them eliminate sources of contamination. This is an excellent approach in that it seeks to correct the problem itself. The Committee encourages the Secretary to aggressively assist States in eliminating sources of unhealthy contamination in fish products. Providing grants specifically for this purpose will be extremely helpful in fulfilling the intent of this legislation.

SANITARY CONDITIONS

The Committee notes that scientific evidence clearly demonstrates that maintaining sanitary conditions regarding the processing, storing and handling of fish products greatly assists in reducing the potential for adulterating the product.

As with meat and poultry processing, storing and handling, fish processing, storing and handling under sanitary conditions, and in a clean environment, will contribute to the production of a more wholesome product.

The Secretary is encouraged to use the authority given the Secretary under the bill to establish guidelines for the training of per-

sons employed in the processing of fish products regarding sanitation and quality control. Such training represents another very cost-efficient method to reduce the incidence of contaminated product found in commerce.

Also, sections 1906 and 1920 of title XIX provide for the issuance of regulations by the Secretary regarding the sanitary, good processing, quality control and handling procedures which establishments and importers should use regarding fish products. This is another important tool for the Secretary to use in reducing the incidence of contaminated product in commerce.

RECALLS

The bill provides the Secretary with an important power. The Secretary may require processors or importers of fish products to recall any fish products that are adulterated or misbranded if the product could cause serious health consequences.

The authority is in addition to any authority the Secretary has to seize and condemn fish products. This requires the processor or importer to assist the Secretary in stopping the further distribution of harmful products.

SHELLFISH INDICATOR RESEARCH PROGRAM

The bill authorizes funding for research regarding shellfish pollution indicators. As discussed earlier, indicators can be used to cost-effectively determine the presence of harmful pathogens on shellfish. The Committee has in mind the National Shellfish Pollution Indicator Study administered by the Louisiana Universities Marine Consortium.

FOREIGN INSPECTION PROGRAMS

The bill requires the Secretary to review the procedures and standards employed by fish product processors and exporters in foreign countries (desiring to export to the United States) to determine whether they meet the requirements and tolerances for fish products at least equal to those established under the bill for domestic fish products.

The intent of this section is to ensure that fish products imported into the United States are at least equal in quality and wholesomeness to that required for U.S. domestic fish products in interstate commerce.

Each foreign country would have to apply to be certified to export to the United States and agree that USDA inspectors could enter their country and inspect products for export to the United States and inspect plants which process fish for export to the United States.

Each such processor and exporter would have to employ, or be subject to, inspection, sanitary, wholesomeness, quality, species verification, residue and other standards and tolerances at least equal to those established for U.S. domestic fish products in interstate commerce. Foreign located plants would be subject to inspection by USDA inspectors to ensure the wholesomeness and quality of the product to be exported to the United States.

Note that this section does not require that each fish processor in the foreign country meet U.S. standards. Processors that produce fish products only for consumption in that country, for example, would not have to meet our requirements. Only the plants in that country that produce for export to the United States are affected by this bill.

USDA presently monitors the results of its foreign inspections of meat and poultry plants through an automated data system which allows it to monitor the performance of foreign plants exporting products to the United States. The Committee assumes that the Department would incorporate fish into this system.

INDUSTRIAL PRODUCTS

Certain species of fish, such as coral, some oysters and menhaden, are used in the production of nonfood products (inedible products) such as jewelry, solvents and animal feeds. The bill is not intended to apply to the processing or handling of these fish or fish products which are not intended for use as human food.

IMPLEMENTATION

The bill provides for an orderly phase-in of the new inspection and sampling program. Under the bill the National Academy of Sciences is to identify chemical and microbiological contaminants and other harmful substances that are most likely to cause fish products to be adulterated. The phrase "most likely" thus refers to those substances that should be addressed as soon as possible by the agencies, FDA and EPA, which will set tolerances under the bill. The Committee notes that the EPA Report contains useful priority lists, toxicity profiles, bioconcentration factors, and other information on chemical contaminants that should be considered by the National Academy of Sciences.

The Committee expects that current inspection activities will be continued at the present level of operation until they are effectively replaced by the program required in this bill.

ADDENDUM—SUMMARY OF MICROBIOLOGICAL CONCERNS

TOXINS OF MICROBIAL ORIGIN

Toxins (i.e. poisons) generated by microorganisms are responsible for "substantial number of cases of foodborne disease." The toxins are produced by algae or bacteria and the problems associated with these toxins normally are found in finfish, not shellfish.

Scombroid fish (Histamine) poisoning

Dr. Taylor[29] notes: Scombroid fish poisoning occurs rather frequently in the United States. This illness has historically been associated with the ingestion of spoiled fish belonging to the scombroid groups: tuna, mackerel, bonito, and Spanish mackerel. However, other types of fish are also commonly implicated in scombroid

[29] Exact language from Dr. Taylor's article, "Marine Toxins of Microbial Origin," is extensively used in this section. Some sentences are omitted or paraphrased.

fish poisoning; these include mahi-mahi, bluefish, jack mackerel, yellowtail, amberjack, herrings, sardines, and anchovies.

Thus, the term scombroid fish poisoning is actually a misnomer, because of the frequent involvement of nonscombroid fish in the disease. The preferred term would be histamine poisoning, since this illness is caused by ingestion of hazardous levels of histamine that have accumulated during the spoilage of the implicated fish.

Histamine poisoning is a worldwide problem occurring rather frequently in any country where consumers ingest any of the fish listed above. The United States, Japan, and Great Britain have reported the greatest number of histamine poisoning incidents.

Histamine poisoning is a chemical intoxication resulting from the ingestion of foods that contain usually high levels of histamine. The incubation period between ingestion of the incriminated fish and the onset of symptoms is rather short, ranging from a few minutes to a few hours. The duration of the illness is also rather short.

Histamine poisoning can be prevented by a variety of measures. With fish, the typical control measure is to hold the fish at low storage temperatures to prevent bacterial growth and histamine formation. Hygienic practices to prevent the contamination of fish with histamine-producing bacteria are not often employed.

Histamine-producing bacteria are usually considered to be part of the normal microflora of the gut, skin, or gills of tuna and other involved species. However, histamine-producing enteric bacteria would not necessarily be expected to proliferate under such conditions.

The Committee especially notes, as pointed out by Dr. Taylor that, "[p]ost-catching contamination may be a very important source of histamine-producing bacteria." Proper chilling of fish is extremely important. It is important to note that the presence of histamine can be quickly determined. Indeed Dr. Taylor notes that, "[g]ood quality assurance programs for the fish typically involved in histamine poisoning should include analysis for histamine. Several rapid methods allow screening of a large number of samples."

Dr. Bauman testified, at the February 7, 1990 hearing, that testing for two key indicators—Staphylococcus aureus and coliforms—would be a very effective method of determining whether good temperature control, and good sanitation conditions existed on the boats. Moreover, since a land-based system is more cost-efficient much more product could be tested, for the same amount of money, for histamines, Staphylococcus aureus and coliforms.

Ciguatera poisoning

Dr. Taylor notes: Ciguatera poisoning results from the ingestion of fish that have become toxic by feeding on toxic dinoflagellates, which are microscopic marine planktonic algae. More than 400 species of finfish have been implicated. The implicated fish are usually bottom feeders or reef fishes.

Larger fish are more frequently implicated than smaller fish of the same species. Among the more commonly implicated species are grouper, barracuda, red snapper, and sea basses. The internal organs of the fish are more toxic than the more commonly consumed muscle tissues.

The microbial toxins associated with ciguatera poisoning primarily affect the gastrointestinal and neurological systems. The onset time for this illness is usually a few hours. A wide variety of symptoms can occur. The moderate-to-severe gastrointestinal manifestations of relatively short duration include abdominal pain, nausea, and vomiting. Moderate-to-severe neurological disorders that may persist for varying periods of time up to several months can occur.

Death due to respiratory paralysis occurs rarely among those individuals who receive prompt medical attention. No antidote exists for ciguatera poisoning. Artificial respiration is the treatment of choice in severe cases where respiratory paralysis occurs. The prognosis for recovery is good if the patient survives the first 24 hours. However, the recovery period can be rather prolonged in some cases.

The toxic dinoflagellates, which cause this problem, are able to proliferate, or bloom, under certain conditions. Apparently, the warm, shallow waters of reef areas are ideal for such blooms. Some fish feed on planktonic algae and will become toxic when a toxin-producing species is involved in the bloom. Larger fish can be affected by ingesting the smaller fish; the toxins can be assimilated through the food chain.

The feeding habits of the fish are important in determining their degree of toxicity. The dinoflagellate blooms in these temperate reef areas can be quite prolonged, and in some cases certain species of fish must be permanently avoided. Some fish may be able to clear the toxins from their systems if the bloom ceases. Larger fish, because of their greater mass and slower growth, probably clear the toxins more slowly.

Paralytic shellfish poisoning

Dr. Taylor notes: Paralytic shellfish poisoning is associated with the ingestion of mussels, clams, cockles, or scallops that have fed on toxic species of dinoflagellates. Fewer cases of paralytic shellfish poisoning have occurred in the United States in recent years, thanks in part to a monitoring and quarantine program. However, paralytic shellfish poisoning is a very serious illness with high fatality rate.

Many of the species of shellfish implicated in paralytic shellfish poisoning are safe to consume except during those times when they are feeding on the toxic dinoflagellates. Thus, paralytic shellfish poisoning tends to occur sporadically. The dinoflagellates bloom as a function of the temperature of the water, light, salinity, presence of nutrients and trace minerals, runoff, winds, and other environmental conditions.

Water temperature is a particularly critical environmental factor influencing the development of blooms. In most cases, the water temperature must be 5–8 degrees C. As the populations of the toxic dinoflagellates increase during one of these blooms, the shellfish in the area begin to become toxic.

Some shellfish can clear the toxins very quickly and are toxic only during the periods of the actual blooms. Other shellfish species, such as the butter clams in the Bay of Alaska, retain the toxins for years and are never safe to consume.

Paralytic shellfish poisoning is a neurological disorder. The onset time is usually less than 1 hour. The duration is variable, but symptoms usually subside within a few days. If the patient survives the first 24 hours, the prognosis for a complete recovery is good. No antidote exists for paralytic shellfish poisoning. Artificial respiration is usually provided in cases where paralysis occurs.

The Committee notes that the best preventative measure is to inspect shellfish from various shellfish beds and test for toxins. If the tests are positive the waters should be closed for harvesting until they are once again safe.

Neurotoxic shellfish poisoning

Dr. Taylor notes that: In the United States, neurotoxic shellfish poisoning has been limited to the Gulf of Mexico and areas off the coast of Florida. A marine dinoflagellate is the causative microorganism in red tides which also causes neurotoxic shellfish poisoning in humans. The red tides are easily identified and are also associated with massive fish kills. Thus, the blooms of this toxic dinoflagellate are readily observed.

The mode of transmission of the toxins to humans is very similar to that discussed above for paralytic shellfish poisoning except that it occurs much more rarely. The filter-feeding molluscs feed on the toxic algae and retain the toxins in their edible tissues.

The symptoms of neurotoxic shellfish poisoning include tingling and numbness of the lips, tongue, throat, and area around the mouth; muscular aches; gastrointestinal complaints; and dizziness. Neurotoxic shellfish poisoning is seldom fatal. The onset time for this illness ranges from a few minutes to a few hours. The duration is also rather short, ranging from a few hours to a couple of days. There is no known antidote for neurotoxic shellfish poisoning.

The Committee notes that the best method of reducing this form of shellfish poisoning is to monitor growing waters for the red tides and prohibit harvesting in danger areas until safe. Such harvesting restrictions are imposed under other Federal and State authorities.

BACTERIAL PATHOGENS OF MARINE ORIGIN

This section describes some of the human illness that can be caused by bacterial pathogens found in seawater as distinguished from bacterial problems introduced by the mishandling of seafood once it is harvested.

A number of illnesses of this type are caused by species of bacteria related to that which causes cholera—*Vibrio cholerae*. In the United States the species that causes by far the most serious problems is *Vibrio vulnificus*.

Vibrio vulnificus

V. vulnificus is a bacterium that occurs in warm coastal waters. It occurs naturally and "high risk" persons can develop a potentially fatal infection. Persons at risk are those with liver disease, cancer, diabetes mellitus, and chronic kidney disease.

Mr. Hackney and Ms. Dicharry note that: This species has been called the new "terror of the deep" and is one of the most invasive species ever described.[30]

Foodborne infection may result after consuming contaminated, raw, or undercooked seafood, particularly oysters and clams, with illness usually starting 16–48 hours after ingestion. The organism penetrates the intestinal tract and produces a primary septicemia. The illness usually begins with malaise, followed by chills, fever, and prostration. Vomiting and diarrhea are uncommon, but sometimes occur shortly after chills and fever.

The fulminating infection progresses rapidly and may cause death in 40-60 percent of the patients. Infection by *V. vulnificus* is rare in normal healthy people. The most common vehicle for the organism is raw oysters.

V. vulnificus is widespread in the environment and has been isolated from estuarine waters of most U.S. coastal States. Infection via the intestinal tract is most often associated with the consumption of raw oysters, but it is sometimes difficult to isolate from the molluscs. It has been demonstrated that the presence of *V. vulnificus* in oysters was probably due to filtration of the bacterium from seawater rather than active multiplication in oysters.

The Committee notes that it is widely recommended that persons in high risk categories avoid eating raw shellfish. When eating shellfish, particularly oysters, be sure that they are properly and thoroughly cooked. The bill provides an enhanced role for the Extension Service of USDA regarding food safety education. The bill also provides funding for grants to States for food safety programs. Advising persons about this risk is, to date, the only effective solution. Controlling the dumping of untreated or poorly treated sewage into our waters would be a major step toward reducing the likelihood of contracting a disease from consuming raw shellfish.

VIRAL DISEASE TRANSMISSION BY SEAFOODS

A major cause of foodborne illness from seafood is sewage contamination of the waters.[31] As Dr. Gerba[32] notes: fish, shellfish and crabs that live in water contaminated by domestic wastes are frequently found to contain enteric bacteria and viruses. However, only shellfish have been implicated in the transmission of enteric viral illness, probably because they are not as thoroughly cooked as other seafoods or are eaten raw.

In addition, shellfish, as filter feeders, tend to concentrate viruses from the water in which they are growing. Bivalve molluscs sieve out suspended food particles from a current of water passing through the shell cavity. Shellfish thus act to concentrate viruses from the water, and viruses may occur in the shellfish at concentrations much higher than in the overlaying water.

---

[30] This section extensively quotes or paraphrases "Seafood-Borne Bacterial Pathogens of Marine Origin," by Cameron Hackney and Angela Dicharry. The entire text of this article is reproduced in appendix II.

[31] *See* "Problems in Protecting Consumers from Illegally Harvested Shellfish," GAO report (HRD–84–36).

[32] Dr. Charles Gerba's article, "Viral Disease Transmission by Seafoods," is extensively quoted in this section. The entire text is set forth in appendix II. Dr. Gerba is Professor, Dept. of Nutrition and Food Science, University of Arizona.

Although there are more than 100 known enteric viruses, only a few have been shown epidemiologically to be transmitted by shellfish: hepatitis A, non-A, non-B hepatitis, Norwalk, Snow Mountain agent, astroviruses, caliciviruses, and small round viruses.

Several epidemiological studies have suggested that shellfish may play a significant role in the transmission of hepatitis A virus. It was reported that 25 percent of the hepatitis A cases in southeast England could be attributed to the consumption of shellfish. Consumption of contaminated molluscs accounted for an estimated 19 percent of the infectious hepatitis in Frankfurt, Germany. Ingestion of raw shellfish was found to be significantly more frequent in infectious hepatitis patients (34/185) than in controls (10/185). Ingestion of steamed clams was more common in patients (13/104) than in matched controls; only 3 of the 13 patients had been exposed to jaundiced persons.

The first documented outbreak of shellfish-associated Norwalk virus gastroenteritis involved more than 2,000 persons throughout Australia. In the United States, the first case of shellfish-associated gastroenteritis attributed to Norwalk virus, and documented as such, occurred in 1980, after individuals consumed oysters from Florida. In 1980 in New York State, there were 103 well-documented outbreaks in which more than 1,000 persons became ill with diarrhea from eating clams and oysters. Norwalk virus was identified in both clam and oyster specimens, as well as serologically in five of seven of the outbreaks.

Committee Consideration

October 24, 1989, Hearing

On Tuesday, October 24, 1989, the Committee on Agriculture, Nutrition, and Forestry met to consider testimony regarding mandatory seafood inspection programs.

As the first to testify, Senate Majority Leader George Mitchell emphasized the bipartisan nature of the issue, the presence of support from the seafood industry and the significant economic impact any mandatory inspection law would have on the fish industry. The Senator pointed out that six House of Representative bills illustrated the need for a comprehensive fish inspection program. According to Senator Mitchell, the USDA is the best agency for implementing a comprehensive program to inspect the Nation's seafood. He estimated the cost at $75 to $100 million per annum, to be funded directly by the Federal Government without utilizing industry user fees.

The next panel consisted of Ms. Jo Ann Smith, Assistant Secretary of Marketing and Inspection for the United States Department of Agriculture, Washington, D.C.; Dr. Frank Young, then Commissioner of the Food and Drug Administration, Washington, D.C.; and Mr. James Brennan, Deputy General Counsel of the National Oceanic and Atmospheric Administration, Washington, D.C.

Accompanying Ms. Smith were Dr. Lester Crawford, Administrator of Food Safety and Inspection Service, Washington, D.C. and Dr. Katherine Adams, Registered Dietician.

Ms. Smith explained the desire of consumers for a seafood supply characterized both by safety and integrity in labeling. According to

Ms. Smith, the addition of a mandatory program regulating the quality of the Nation's seafood is roughly analogous to the previous addition of poultry to the flesh food inspection programs.

The meat and poultry inspection program consists of 7,500 inspectors and 1,200 veterinary medical officers assigned to those production facilities involved in interstate or foreign commerce. Programs are coordinated with States in order to maintain uniformity in the caliber of the food supply. Food Safety and Inspection Service (FSIS) personnel are trained and supervised by 189 inspection circuits, 26 area offices, 5 regional offices and the Washington office. Dr. Crawford noted that USDA carries out a hands-on review while looking to the FDA, EPA and private sector experts in order to set tolerance levels.

Ms. Smith commented on the extensive network of public and private laboratories capable of analyzing the composition of seafood and testing for various microbiological and chemical threats. She noted the importance of an inspection system tailored to preventing problems and minimizing delays because of the highly perishable nature of seafood. In-plant procedures regarding the rapid testing of meat and poultry proved effective in ascertaining the presence of certain harmful chemicals.

Ms. Smith reported that the best means of ensuring the safety of seafood would be to implement the Hazard Analysis Critical Control Point (HACCP) method, already in limited use with current inspection programs. HACCP emphasizes inspection at crucial points in the processing, storage and handling of food. Additionally, present inspection programs could be expanded to ensure that imported seafood met domestic standards.

Ms. Smith noted that the implementation of a mandatory inspection program would presumably include a consumer education and outreach effort. Such an approach, coupled with an FSIS labeling policy, could reduce the risk of economic fraud and add to the protection of the Nation's seafood supply. She pointed out that in FY 1988 FSIS home economists answered over 50,000 consumer calls regarding all aspects of food safety.

Dr. Frank Young, former Commissioner of FDA, stated that foodborne illnesses derived from seafood do not pose a substantial threat to the public health. He noted that although consumption of seafood has increased, the level of illness has remained constant. Dr. Young recognized the complexity of a program encompassing concerns as varied as harvesting, laboratory procedures and general administration.

The former Commissioner explained the existing program of voluntary inspection. In conclusion, Dr. Young viewed periodic inspections of fishing vessels and use of the HACCP method as possible areas of improvement in the prevailing approach to inspection.

Mr. Brennan was accompanied by Thomas Billey, Director, Trade and Industry Service, National Marine Fisheries Service. Mr. Brennan recognized NOAA's experience in the inspection and regulation of the 500 different species of fish of which 100 species are harvested by 100,000 vessels in the United States.

According to Mr. Brennan, HACCP would be most effective in the prevention of problems and enforcement of seafood inspection provisions, especially in regard to sanitation standards, the discov-

ery of contaminants and the prohibition of harvesting from certain contaminated areas. Enforcement could be improved by the registration of vessels and production facilities and giving additional authority to inspectors. Additionally, Mr. Brennan recommended coordination with both the appropriate State and foreign agencies. He proposed that States receive Federal grants covering a segment of the cost for programs approved by the FDA.

Mr. Brennan recommended that user fees be charged to fund any increase in Federal inspection of seafood. Mr. Brennan described NOAA's experience in managing the availability of harvestable areas according to their safety, thus promoting a cost effective and efficient program relying on one agency to regulate the activities of commercial sea vessels. NOAA would best be able to handle problems associated with the complexities of species and geographical harvests and the perishable nature of seafood.

The second panel consisted of Ms. Ellen Haas, Director of Public Voice, Washington, D.C.; and Lee Weddig, executive vice president of the National Fisheries Institute.

Ms. Haas expressed concern about what she perceived as the lack of an adequate program to protect the consumer. She noted that while consumption of fish increased 20 percent from 1980 to 1987, fish remains the only flesh food not subject to mandatory, comprehensive inspection. Consumer safety problems are compounded by the unique nature of seafood products. Along with a relatively quick deterioration process, seafood is harvested in an unsupervised environment and tends to be more susceptible to contamination than other food products. Ms. Haas exhibited statistics showing fish to be 3 times as likely to cause illness as beef, and 1.5 times as likely to cause illness as poultry. She was alarmed by the presence of toxins in harvesting and growing waters resulting from various industrial and agricultural chemical uses.

Ms. Haas emphasized that the current FDA administered inspection program was inadequate because three-quarters of the seafood processing firms and 100 percent of commercial ocean vessels were not subject to inspection. Lastly, Ms. Haas recommended that USDA administer the inspection program, with standards set by FDA.

Mr. Weddig pointed to the economic importance of a seafood industry that generated $25 to $30 billion, over one million jobs and the most exports of seafood in the world. He stressed that the United States could encounter difficulty with foreign markets due to the lack of a mandatory safety inspection program. According to Mr. Weddig, the fish industry has undergone a slump in the past two years, largely due to decreasing consumer confidence. Alas, Mr. Weddig emphasized that only USDA's combination of foreign and domestic resources could initiate a comprehensive inspection program. An increase in aquacultural farming necessitated USDA involvement as well.

MARKUP

The Committee met in open session on Thursday, May 22, 1990, to markup S. 1245, the Fish Safety Act of 1990. Chairman Leahy offered an amendment in the nature of a substitute to S. 1245. The

amendment struck all the language in S. 1245 and replaced it with new text. The Committee accepted Chairman Leahy's amendment in the nature of a substitute.

Senator Cochran then offered an amendment to strike section 1923 (whistleblower protection) from the bill. Senator Cochran emphasized that a comprehensive whistleblower protection bill was reported out of the Labor Committee. He opposed the whistleblower section in the markup vehicle on the grounds that it would be duplicative of that other bill.

Chairman Leahy made the point that whistleblower protections were an important safeguard—protecting freedom of speech and public safety. Whistleblowers could help USDA enforce the law. Under the bill USDA inspectors would not be continuously present at processing plants. This section would protect employees who wanted to inform the Department of Agriculture or the employer of violations of the Fish Safety Act. He noted that any labor dispute issues would be covered by the Department of Labor.

Senator Bond supported Senator Cochran's amendment and argued that the whistleblower language would set new standards for employee-employer relationships not available under other Federal private whistleblower laws. Chairman Leahy pointed out that the standard of proof in this bill is basically the same as in the Whistleblower Protection Act of 1989 which the Congress recently passed.

Senator Daschle said that the legislation did not go far enough and he preferred continuous inspection but without it, the whistleblower section is necessary. Chairman Leahy agreed and pointed out that these protections already apply to private sector employees in other public health areas. Senators Leahy and Daschle also agreed that this was a fair compromise but if the whistleblower language was stricken from the bill, there would be a move on the floor to either adopt continuous inspection or stronger whistleblower language.

Senator Bond asked legal counsel to explain the standards of proof in the proposed bill. Counsel, Mr. Barron, pointed out that there were two relevant standards of proof. Mr. Barron explained that the bill would allow the employee an opportunity to prove that the protected speech (the whistleblowing) was a contributing factor in the adverse personnel action.

Counsel Barron pointed out that even if the employee proved that the whistleblowing contributed to the personnel action that the employee would not necessarily be able to obtain relief. The employer would have an opportunity to demonstrate, by clear and convincing evidence, that the employer would have taken the same personnel action in the absence of the protected whistleblowing. In cases where employers made that case, the employee would not be entitled to relief.

Counsel Barron further noted that the dual burden of proof procedures were taken from the Whistleblower Protection Act of 1989 which applied to Federal employees.

Senator Bond inquired as to whether the clear and convincing evidence standard was higher than any related standard of proof found in other Federal whistleblower protection legislation protecting private employees. Counsel Barron noted that the burden on

the employer was higher than for other legislation regarding private, non-Federal, employees.

After further discussion on the whistleblower language, Senator Cochran offered a motion to postpone consideration. Chairman Leahy offered to vote on the amendment and Senator Cochran withdrew his motion to postpone consideration. Senator Cochran's amendment was accepted by a rollcall vote of 10–9.

SUMMARY OF MAJOR PROVISIONS

The Fish Safety Act of 1990 will establish a comprehensive fish inspection program that is aimed at ensuring public confidence in the safety of fish and fish products. This fish inspection program includes the following major elements:

The U.S. Department of Agriculture, through its Food Safety and Inspection Service, would conduct inspections of fish, fish products, and fish processing establishments.

Like current programs for inspecting meat and poultry, the fish inspection program would be mandatory and it would be funded by the Federal Government. However, unlike the current meat and poultry program, inspectors would not be continuously present in all processing establishments.

Tolerances identifying unsafe levels of certain contaminants would be established on the basis of scientific analysis by the U.S. Food and Drug Administration and in some cases by the Environmental Protection Agency.

Standards for sanitation and labeling would be established by the Department of Agriculture.

Fish and fish products that do not meet the established tolerances would be removed from the commercial market; fish and fish products that satisfy the standards would receive a Federal seal.

States that establish inspection programs for interstate commerce at least equal to the Federal program can be authorized to conduct the inspection program. Up to 50 percent of the cost of a State program would be provided by the Federal Government.

Processing establishments, including vessels which process fish, would be subject to periodic inspection, and would have to be certified by the Department of Agriculture. Other vessels, such as commercial fishing vessels, recreational vessels, or fish tender vessels, would not be subject to periodic inspection and would not be certified.

Procedures to identify harvest areas which may produce contaminated products would be established.

Imports would have to meet inspection standards that are at least as stringent as those affecting domestic fish products.

The Department of Commerce, in conjunction with the States, would establish a system for identifying and classifying fish and shellfish growing and harvesting areas for coastal areas and the Great Lakes. The Secretary of Commerce could close areas under its jurisdiction to the harvesting of a certain fish or shellfish species in certain circumstances.

A substantial program for consumer education and fish safety research would be established.

Federal funding and other assistance would be available to States for conducting activities related to improving the quality of fish products including Federal assistance for State inspection programs for products in intrastate commerce.

The Fish Safety Act of 1990 requires that the Secretary of Agriculture, the Secretary of Commerce and the Commissioner of the Food and Drug Administration implement this fish inspection program within three and a half years. Current law will continue until the new law is phased in.

SECTION-BY-SECTION ANALYSIS OF THE FISH SAFETY ACT OF 1990

The bill requires the Department of Agriculture to administer a comprehensive fish inspection program to protect consumers and maintain public confidence in our food supplies. Like current programs for meat and poultry inspection, the fish inspection program would be mandatory and it would be funded by the Federal Government.

The Food and Drug Administration would continue its regulatory function of setting tolerances for certain harmful contaminants, based on scientific analysis, as set forth in the bill.

Many provisions in the bill are based on the Poultry Products Inspection Act, the Federal Meat Inspection Act and the Federal Food, Drug and Cosmetic Act. Standards for sanitation and labeling would be established by the Department of Agriculture. States will be able to administer this program on behalf of the Secretary and receive up to a 50–50 Federal funding match.

This new program is not based on the continuous presence of Federal inspectors. It is based instead on cost-effective monitoring principles which focus efforts on "critical control points" and on "spot-checking" samples of fish products to monitor compliance with the goals of the program.

The Commerce Department would continue its major responsibilities regarding coastal waters and vessel regulation.

The bill creates a new title XIX to the Food Security Act of 1985.

SECTION 1901. DEFINITIONS

This section sets forth detailed definitions of terms used in the bill. The critical definitions of "adulterated" and "misbranding" are modeled after the definitions found in the Poultry Products Inspection Act and the Federal Meat Inspection Act with certain additional requirements.

SECTION 1902. EXCEPTIONS AND EXCLUSIONS

Vessels, other than vessels which process fish onboard, will not be subject to potential inspection by USDA inspectors.

SECTION 1903. FEDERAL AND STATE COOPERATION

The bill authorizes three types of fish inspection programs: State administered for *intrastate* commerce; State administered on behalf of the Secretary for *interstate* commerce—with an up to 50 percent Federal funds match; or a federally administered funded and operated fish inspection program.

Intrastate.—The Secretary may assist any State in developing and administering a State fish product inspection program. This applies to any State which has enacted a mandatory State fish product inspection law that imposes inspection, sanitation and other requirements that are at least equal to those under this title.

The fish approved under these *intrastate* commerce programs shall not bear any official marks of the Secretary or certificates and any State or local labels on such products must clearly indicate that the product is for *intrastate* commerce only.

Warning notice.—If the Secretary determines that a State fish inspection program is not at least equal to the program established under this title the Secretary shall promptly notify the Governor of the State of such determination.

Notice.—After consulting with the State and providing an opportunity for the State to promptly correct any deficiencies, if the Secretary determines that a State fish inspection program does not have standards that are at least equal to those under this title the Secretary shall promptly notify the Governor of the State of such determination and shall terminate Federal assistance. If public health is clearly at risk in these circumstances the Secretary may subject the State to the inspection provisions of the bill as though the fish products were in commerce.

Interstate commerce.—The Secretary may cooperate with State agencies regarding the State administration of the inspection and sampling aspects of the program on *behalf of the Secretary.*

This inspection program must be at least equal to that established for the Secretary—and the Secretary shall issue regulations on this matter.

The Secretary shall monitor and evaluate each such program administered on behalf of the Secretary by a State on an ongoing basis to assure compliance with regulations and other requirements of the Secretary.

Financial assistance.—States that operate this program get up to a 50-50 match of Federal funding.

Plan of operation.—Each State approved by the Secretary to administer the program for the Secretary shall annually submit to the Secretary a plan of operation setting forth:

How the State intends to administer the program consistent with this title;

Cost projections setting forth anticipated State costs in administering the program on behalf of the Secretary;

Estimates of staffing, equipment, and other requirements and indicators of expected performance in the State administration of the program; and

Procedures for the making of advance Federal payments, and financial recordkeeping, regarding the Federal share of the total cost of the cooperative programs.

Federal program.—For States in which the State administered inspection program is not in place, the Secretary shall administer a comprehensive inspection program for fish products intended for human consumption designed to protect the consuming public from adulterated, misbranded or mislabeled fish and fish products.

The inspection program of the Secretary shall—

(1) be specifically designed to take into consideration the special characteristics of fish species and fish products;

(2) be based upon a comprehensive assessment of fish and fish products and their processing and handling that identifies the hazards and assesses the severity of the hazards and risks, and that prescribes standards for sanitation in the processing of fish and fish products for the protection of consumers;

(3) be also based on:

identifying and assessing the severity of the potential health risks associated with fish, fish species, and fish products and with their processing and handling;

determining sources and specific points of potential contamination which may adulterate fish and fish products; and

the need to require procedures to prevent, eliminate or control potential contaminants which may adulterate fish and fish products and the need to monitor those procedures;

(4) assure, through frequent, and unannounced, or announced, inspections of establishments that the processing of fish and fish products complies with the standards for good sanitation, manufacturing, processing, storage, temperature control, packaging, and handling;

(5) provide for the identification and classification of growing and harvesting areas in conjunction with the appropriate Federal and State agencies; and

(6) provide for the sampling and testing of fish products;

(7) establish procedures to aid the Secretary in determining sources of contamination, including determining which harvesting or growing areas are likely to produce fish which are adulterated; and

(8) provide regulations setting forth rules for the identification, naming, labeling and fill of containers regarding fish or fish products intended for human consumption taking into consideration current industry practices and Federal regulations.

Tolerances for fish and fish products.—The Commissioner of Food and Drugs shall set tolerances (except where such tolerances are set by the Administrator of the Environmental Protection Agency) for poisonous or deleterious substances under the definition of adulteration (section 1901(a) (1) and (2)) that shall be used by the Secretary of Agriculture, to determine instances in which fish or fish products capable of use as human food will be considered adulterated (injurious to human health).

Any such tolerances will be set at a level such that the fish products capable of use as human food are not injurious to health. Such tolerances shall be established in consultation with: the National Academy of Sciences, the Environmental Protection Agency, the Centers for Disease Control, the Secretary of Agriculture, the Secretary of Commerce, and the Interstate Shellfish Sanitation Conference.

FDA shall review and reconsider any such tolerances regarding fish products as new scientific information or new technologies become available.

Contaminants.—Tolerances shall be established by FDA for harmful chemicals (except where tolerances are established by the Administrator of the Environmental Protection Agency), toxins, parasites, pathogenic microorganisms, viruses, bacteria, and other harmful agents, which may render fish and fish products adulterated.

Indicators.—In establishing such tolerances for contaminants FDA may include the use of indicators, including indicator organisms, from which it may reasonably be inferred that an injurious contaminant or substance is present whenever the contaminant or substance itself cannot be cost-effectively detected.

SECTION 1904. GROWING AND HARVESTING AREAS

Identification of growing areas.—The Secretary of Commerce, for waters exclusively under the Secretary's jurisdiction, and appropriate State authorities for waters under the appropriate State's jurisdiction, shall by regulation establish a system for the identification and classification of growing and harvesting areas for fish in coastal areas and the Great Lakes.

Action by the Secretary of Agriculture.—The Secretary of Agriculture, upon identifying significant instances or trends of contamination, based on the sampling and analysis of fish and fish products, that may represent significant threats to public health and safety in fish harvested from specifically identified growing and harvesting areas, shall so inform appropriate State or Federal agencies.

Within 30 days after receiving such notice from the Secretary of Agriculture, each of the notified authorities shall provide a written response informing the Secretary of Agriculture of any known violations of applicable regulations under their respective authorities, and describing any remedial actions that have been taken, within the specified area.

Grants to States.—The Secretary may provide States with financial and other assistance to prevent entry of adulterated fish into establishments including annual grants to each State that is a member of the Interstate Shellfish Sanitation Conference.

Action by the Secretary of Commerce.—In the case of public health emergencies the Secretary of Commerce may close waters under the Commerce Secretary's jurisdiction, or otherwise restrict the harvesting of a fish species in waters under the Commerce Secretary's jurisdiction.

The Secretary of Commerce shall periodically review the growing and harvesting areas closed or restricted under this section to determine whether any such area should no longer be so designated.

The Secretary of Commerce shall give reasonable public notice, except in cases determined to be public health emergencies, before any closure or restriction action is taken under this section.

SECTION 1905. POWER OF INSPECTORS

Actions of inspectors.—Inspectors authorized by the Secretary to conduct inspections under this title (including State employees so authorized) shall take such actions as are necessary in the judgment of the inspector.

Such actions include: the inspection of establishments, fish and fish products, packages, containers, labels, equipment, processing procedures, and records; the sampling of fish products; the detention and condemnation of adulterated or misbranded fish products; and the inspection of imports of fish products.

Condemned fish and fish products.—All fish and fish products found by the Secretary to be adulterated or misbranded shall be immediately segregated, seized, and, if objection is not made within 48 hours, condemned. If objection is made, such fish or fish product that are in perishable form may be processed to the extent necessary to prevent spoilage pending hearing and judicial review.

SECTION 1906. SANITARY CONDITIONS

Each establishment shall maintain premises, facilities, and equipment, and the operation of such, in accordance with such sanitary practices as are required by regulations promulgated by the Secretary for the purpose of preventing the entry into, or flow or movement in commerce, or burdensome effect upon commerce, of fish or fish products which are adulterated.

SECTION 1907. CERTIFICATION OF ESTABLISHMENTS, IMPORTERS

The Secretary shall establish procedures for the annual certification, or decertification for good cause, of establishments (fish processing plants or fish processing vessels), and persons engaged in the importing of fish or fish products. The Secretary shall require such information as the Secretary determines appropriate including the name of the owner and operator of the establishment, or import business, the principal place of business, and a list of each type of fish or fish product typically processed, handled, or imported by each such establishment or importer. No establishment or importer may process or handle any fish or fish product for commercial purposes unless such establishment, or importer, is certified by the Secretary.

Refusal to certify or revocation.—If an establishment certified under the program fails to comply with any requirement of this title or regulations promulgated under this title, the Secretary may, after notice and an opportunity for a hearing, either revoke the certification, suspend the certification for a period of time, or impose conditions and restrictions on the certification as the Secretary determines are necessary and appropriate.

SECTION 1908. LABELING, PACKAGING AND MARKING

Labeling or other markings.—All fish products processed at any certified establishment, and which are not found to be adulterated, shall at the time they leave the establishment bear information as the Secretary may require. The Secretary may permit the use of a seal on such processed products which states that the contents are processed in accordance with Federal standards or such similar wording as the Secretary determines is appropriate.

Protection of public.—The Secretary may prescribe: the styles and sizes of type to be used for marking and labeling; definitions and standards of identity or composition of articles and standards of fill for such articles not inconsistent with any such standards es-

tablished under the Federal Food, Drug, and Cosmetic Act. Under procedures developed by the Secretary, the Secretary shall permit statements on labels which indicate the State or location of origin of the product.

No sales.—No article shall be sold or offered for sale in commerce by any person, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading, approved by the Secretary, are permitted.

SECTION 1909. RECORDS, REPORTS AND DISCLOSURE

Establishments shall maintain accurate records regarding the receipt, delivery, sale, movement, or disposition of fish or fish products; matters reasonably related to whether fish or fish products may be adulterated or misbranded; and other activities and matters relevant to food safety and sanitation.

Access to records.—The Secretary of Agriculture shall, upon request at reasonable times, have access to and make copies of records maintained pursuant to this title.

SECTION 1910. IMPORTS

No fish or fish product may be imported for consumption in the United States, unless such fish or fish product is not adulterated or misbranded, complies with all standards of the Secretary applicable to fish or fish products in commerce in the United States, is marked and labeled as required by regulations for imported articles, and complies with this title.

Inspection of imports.—The Secretary shall enforce this section through inspections and other procedures, and the sampling and inspection of fish or fish products that are offered for importation, for consumption in the United States.

Corrective actions.—All fish or fish products that are refused entry pursuant to subsection or that are entered, or withdrawn from warehouse, for consumption in the United States in violation of this section shall, pursuant to regulations, be destroyed unless such fish and fish products are exported within a time fixed by the Secretary or the Secretary determines that such fish and fish product can be brought into compliance with this title by relabeling or other action.

Costs.—Storage, cartage, labor, and other costs resulting from the denial of entry, or withdrawal from warehouse, of any fish or fish product shall be paid by the owner or consignee, and nonpayment of such costs shall constitute a lien against such product and any other fish or fish product thereafter entered, or withdrawn from warehouse, for consumption in the United States by such owner or consignee.

Foreign seafood inspection program.—Upon request, the Secretary shall review the fish inspection program of each country desiring to export fish or fish products into the United States to determine if such program is at least equal to the program established under this title.

If the Secretary determines that a country desiring to export fish or fish products to the United States has a fish inspection program at least equal to the program established under this title and that such country will permit the necessary enforcement measures, the Secretary shall issue a certificate to such country stating that the country maintains such a program. The consideration of any application for certification shall include the inspection of individual establishments to ensure that the inspection program of the foreign country involved is meeting U.S. standards and tolerances.

No fish or fish product shall be permitted entry into the United States from a country that does not have such a current, valid certificate.

Reports to Congress.—Not later than March 1 of each year the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition and Forestry of the Senate a comprehensive and detailed written report with respect to the administration of the foreign program.

SECTION 1911. EXPORTS

Standards.—Fish or fish products intended for export to a foreign country shall not be deemed to be adulterated or misbranded if they are consistent with the specifications of the foreign purchaser; are not in conflict with the laws of the country to which they are intended for export; are labeled on the outside of the shipping package that they are intended for export; and are not sold, offered for sale, or otherwise disposed of in commerce within the United States except that such fish or fish product shall be deemed to be adulterated if the Secretary determines it represents a threat to the health of the eventual consumer.

Inspection.—The Secretary shall inspect fish or fish products intended to be exported to foreign countries at such times and places and in such manner as the Secretary deems necessary.

Certificates.—The Secretary shall, upon request of the exporter, provide a certificate for export stating the condition of fish or fish products inspected under this section.

SECTION 1912. RECALL

The Secretary may require any person who owns or operates an establishment or other facility engaged in the processing of fish or fish products, or in the importing of fish or fish products, to recall any fish or fish products which are adulterated or misbranded if the Secretary finds that such fish or fish products are adulterated or misbranded and could cause serious health consequences.

SECTION 1913. COOPERATION WITH CENTERS FOR DISEASE CONTROL

The Secretary of Health and Human Services shall establish, through the Centers for Disease Control, an active surveillance system, based on a representative proportion of the population of the United States, to provide an accurate estimate of the frequency of human disease in the United States associated with the consumption of food, including a comparison of each major food category.

SECTION 1914. PROHIBITED ACTS

The following acts are prohibited:

(1) The processing or sale of any fish or fish product that is adulterated or misbranded within the meaning of section 1901 or 1903 of this title.

(2) The refusal to permit entry to or inspection of any establishment, or to otherwise interfere with any inspector or other person in carrying out the duties required under this title or under regulations implementing this title.

(3) The sale, transportation, or offer for sale or transportation, in interstate commerce of any fish or fish product that is adulterated or misbranded at the time of such sale, transportation, or offer for sale or transportation.

(4) The possession by any establishment of fish or fish products except in compliance with the requirements of this title or regulations issued under this title.

(5) The commission of any act, or the omission of any act, while such fish or fish product is being transported in interstate commerce or held for sale after such transportation, that is intended to cause or has the effect of causing such fish or fish product to be adulterated or misbranded.

(6) The sale, transportation, or offer for sale or transportation, in interstate commerce of any fish or fish product that is not processed in accordance with the requirements of this title or any regulations promulgated thereunder.

(7) The reproduction, alteration, or destruction of any official stamp or certificate without the authorization by the Secretary.

(8) The misbranding of fish or fish products, or the creation or maintenance of records that are false either by content or omission, or destruction of records containing information required under this title.

(9) The handling or processing for interstate commerce of fish or fish products in any establishment unless there is in effect for such establishment a certification issued by the Secretary.

(10) The importation into the United States of fish or fish products which are capable of use as human food if such articles are adulterated, labeled or packaged in a false or misleading way, or otherwise misbranded, or fail to comply with all the inspection, good processing practices, and other provisions of this bill and regulations issued thereunder applicable to such articles in interstate commerce within the United States.

SECTION 1915. CIVIL PENALTIES

Any person who violates any provision of this title, or the regulations issued pursuant thereto, shall be liable to the United States for a civil penalty, after notice and opportunity for a Federal court hearing, in an amount not to exceed $5,000 for the first violation, and the total fine shall increase by 10 percent for each subsequent violation. The bill provides an opportunity for Federal court (United States District Court) review of the matter before the fine is paid.

In determining the amount of such penalty, the Secretary shall take into account the gravity of the violations and, with respect to

the violator, the degree of culpability and history of prior violations, and such other matters as justice may require.

SECTION 1916. CRIMINAL PENALTIES

Any person who intentionally violates section 1903, 1908, 1910 or 1914 of this title, or regulations issued thereunder, may be fined in an amount not to exceed $10,000, or imprisoned for not more than 1 year, or both, and if such intentional violation involves intent to defraud, or any distribution of any fish or fish product that is adulterated or misbranded, be fined in an amount not to exceed $20,000, or imprisoned for not more than 3 years, or both.

Notice of warning.—In the case of one or more minor violations of this title or regulations promulgated under this title, the Secretary may, whenever the Secretary believes that the public interest will be adequately served thereby, issue to the violator a suitable written notice of warning.

In determining whether the public interest will be adequately served by a written notice of warning, the Secretary shall consider, among other factors: the compliance history of such person; the magnitude of the violation; whether compliance with this title would likely be obtained as a result of such notice; and whether such violation is of a minor or technical nature.

Before any violation of this section is reported by the Secretary to any U.S. attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given reasonable notice of the alleged violation and opportunity to present his or her views orally or in writing with regard to such contemplated proceeding. The preceding sentence shall not apply in those cases where it is determined that such notice would significantly interfere with the ability to prosecute the violation.

SECTION 1917. CARRIERS

Liability.—No common carrier or contract carrier shall be subject to penalties under this title for the receipt, carriage, holding, or delivery, in the usual course of business, as a carrier, of any adulterated or misbranded fish or fish product owned by another person, unless the carrier during the time of such receipt, carriage, holding, or delivery, had knowledge or was in possession of facts that would cause a reasonable person to believe that the fish or fish products were adulterated or misbranded or were otherwise not eligible for transportation under this title, or refuses to furnish on request of the Secretary the name and address of the person from whom the carrier received the adulterated or misbranded fish or fish product, and copies of all documents pertaining to the delivery of such fish or fish product.

SECTION 1918. HEARINGS AND SUBPOENAS

Administrative hearings.—Except regarding criminal prosecutions and certain other exceptions, the Secretary shall afford an opportunity for a hearing, under procedures issued by the Secretary, to any person allegedly adversely affected by the action or inaction of the Secretary under this title. These procedures shall include an

opportunity to present evidence, the right to be heard in person or by counsel, and other rights.

Subpoenas.—The Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of any documentation or other evidence that relates to any matter under investigation or in dispute.

The Secretary shall pay witnesses subpoenaed under this subsection customary reasonable fees and transportation expenses.

Interim relief.—Sixty days after a final order is issued by the Secretary, the Secretary may take any actions deemed necessary. The Secretary may take emergency actions if necessary during the pendency of judicial review.

Judicial review.—Any person adversely affected by the Secretary's action on such person's objections may obtain judicial review by filing in the United States court of appeals for the circuit in which he or she resides or where his or her principal place of business is located, within 60 days after the entry of the Secretary's order, a petition for judicial review.

SECTION 1919. OTHER CRIMES

Bribing or assaulting inspectors is made a serious criminal offense.

SECTION 1920. REGULATION OF PRODUCTS AND ESTABLISHMENTS

Processing.—Each establishment or vessel subject to inspection under this title shall be operated in accordance with such sanitary, good processing, quality control, and handling procedures or practices as are required in regulations promulgated by the Secretary.

Stamp.—The Secretary shall by regulation prescribe standards for identifying and otherwise marking fish or fish products, or their packages or containers, with an official stamp which regulation shall ensure is available only for fish and fish products that are processed or handled in accordance with the requirements of this title.

Storage or handling regulations.—The Secretary shall by regulation prescribe conditions, except for restaurants and retail stores, under which fish and fish products capable of use as human food, shall be stored or otherwise handled by any persons engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, such articles, whenever the Secretary deems such action necessary to assure that such articles will not be adulterated or misbranded when delivered to the consumer. Violation of any such regulation is prohibited.

Record keeping.—The Secretary shall publish regulations providing for the preparation and maintenance of records specifically describing all activities relevant to food safety and sanitation.

SECTION 1921. RESEARCH AND EDUCATION

Research.—The Secretary shall, in consultation with other Federal agencies and with the States, establish priorities for fish and fish products safety research, such as test methodology for microbiological and chemical contaminants, and the appropriate Federal agencies shall conduct research regarding those priorities.

Education grants.—Each fiscal year, out of the funds appropriated to carry out this title, the Secretary of Agriculture through the Extension Service of the Department of Agriculture, shall use $2,000,000 to provide demonstration project grants to States to assist States in providing food safety information and instruction regarding the proper handling, storage and preparation of fish and fish products for human consumption.

Shellfish research indicator program.—The Secretary of Commerce shall establish and administer a 5-year shellfish indicator research program to develop a system of classification of shellfish harvesting areas based upon the latest technological advancements in microbiology and epidemiological methods.

Periodic review.—The Secretary shall review the research program authorized by this section not less than once every 2 years and, on the basis of that review, make changes in the administration of the program that are appropriate to carry out more effectively the activities described.

Research study regarding inspections of harvesting and fish tender vessels.—The Secretary, together with the Secretary of Commerce shall, not later than 2 years after the date of enactment of this title, complete and conduct a study of:

(i) the role of fish tender and fish harvesting vessels regarding the wholesomeness of fish and fish products;

(ii) the potential need to require vessels to register with the Secretary of Commerce; and

(iii) based on a scientific analysis, the necessity of including any particular type or class of such vessels in the inspection program, or a vessel registration program conducted pursuant to this title.

If as a result of this study or any update of such study the Secretary concludes, in consultation with the Secretary of Commerce, that any type or class of vessels not subject to inspection should be subject to inspection, the Secretary shall so advise the appropriate committees.

Other research.—The Secretary shall conduct and support research with respect to testing the methodology for detecting and measuring biological and chemical contaminants in fish and fish products; techniques and procedures for inspecting fish and fish products; sanitation practices for the harvesting, handling, processing, transportation, and storage of fish and fish products; and any other matters that may further the purposes of this title.

Reports to Congress.—The Secretary of Agriculture and the Secretary of Commerce shall submit a biennial report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate regarding research and education program authorized under this section.

SECTION 1922. MISCELLANEOUS

This section includes: (1) procedures to be used to condemn adulterated or misbranded fish products; (2) prohibitions on the improper copying of official marks; (3) provisions allowing the Secretary to ban the entry of certain products into establishments; and (4) lan-

guage providing for the severability of provisions of the bill should some sections be held unconstitutional by the courts.

SECTION 1923. REGULATIONS

Issuance.—The Secretary of Agriculture shall issue regulations necessary or appropriate to carry out this title in accordance with the informal notice and prior public comment requirements of section 553 of title 5, United States Code.

Copy and justification.—Five days prior to issuing any regulation referred to in this section, the Secretary shall provide to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a copy of the regulation and a detailed statement justifying the regulation.

SECTION 1924. INTERAGENCY COOPERATION

By agreement with the head of any Federal agency, the Secretary may utilize on a reimbursable basis or otherwise, the personnel, services, and facilities of any other department or agency of the United States in the performance of his duties under this bill.

SECTION 1925. EXEMPTIONS FROM FEDERAL FOOD, DRUG AND COSMETIC ACT

The inspection, sampling or regulation of fish products, and the handling, processing, storage, or transportation of fish products, shall be exempt from the Food, Drug and Cosmetic Act to the extent that this new title XIX applies to such fish products, or the handling, processing, storage, or transportation of fish products.

SECTION 1926. COST OF INSPECTION, OVERTIME

The cost of USDA inspection services rendered shall be borne by the United States except for overtime and holiday work performed by inspectors which shall be paid by the establishments affected.

SECTION 1927. AUTHORIZATION OF APPROPRIATIONS

Inspection program.—There are authorized to be appropriated, to carry out this title, not to exceed $14,000,000 for fiscal year 1991, $40,000,000 for fiscal year 1992, $80,000,000 for fiscal year 1993, and $100,000,000 in each of fiscal years 1994 and 1995.

Research program authorization.—Of the funds authorized to be appropriated under subsection, there are authorized to be appropriated to the Secretary not to exceed $5,000,000 for each fiscal years 1991, 1992, and 1993, for carrying out the research program authorized by section 1921.

SECTION 1928. EFFECTIVE DATE

The bill is effective on the date of enactment. Note that sections 5 through 7 of the bill provide for phase-in periods for the implementation of various aspects of the bill.

Implementation.—The bill (sections 5 through 7) sets forth a detailed schedule for implementation by the Secretary of Agriculture,

the Commissioner of Food and Drugs, and the Secretary of Commerce.

Cost Estimate

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate, the Committee has included the cost estimate by the Congressional Budget Office.

U.S. Congress,
Congressional Budget Office,
Washington, DC, June 19, 1990.

Hon. Patrick J. Leahy,
Chairman, Committee on Agriculture, Nutrition and Forestry, U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for S. 1245, the Fish Safety Act of 1990, as ordered reported by the Senate Committee on Agriculture, Nutrition and Forestry on May 22, 1990.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

Robert F. Hale
(For Robert D. Reischauer, Director).

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number S. 1245.
2. Bill title: Fish Safety Act of 1990.
3. Bill status: As ordered reported by the Senate Committee on Agriculture, Nutrition and Forestry on May 22, 1990.
4. Bill purpose: To amend the Food Security Act of 1985 to expand the meat inspection programs of the United States by establishing a comprehensive inspection program to ensure the quality and wholesomeness of all fish products intended for human consumption in the United States, and for other purposes.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1991	1992	1993	1994	1995
Estimated authorization levels:					
Fish Safety Provisions	14	40	80	100	100
Extension Service Programs	1	1	1	1	1
FDA Reduction	0	0	0	−19	−20
Total estimated authorization levels	15	41	81	81	81
Estimated outlays:					
Fish Product Safety Provisions	13	38	76	98	100
Extension Service Programs	1	1	1	1	1
FDA Reduction	0	0	0	−16	−19
Total estimated outlays	13	38	77	83	82

Details in this table may not add to totals because of roundng. The costs of this bill fall within budget functions 370 and 550.

Basis of estimate: S. 1245 would authorize the Secretary of Agriculture to establish a fish and fish product inspection program and to assist States that choose to implement their own inspection programs. The bill would also authorize the Commissioner of Food and Drugs to establish standards for contaminants in fish that are safe for human consumption. In addition, the bill would require the Secretary of Commerce to identify and classify the growing and harvesting areas for fish in coastal areas and the Great Lakes. Authorization levels for these provisions were stated in the bill.

S. 1245 would authorize the Secretary of Agriculture, through the Extension Service, to disseminate information on the proper handling and preparation of fish and fish products. The bill provides an authorization level of $750,000 in each of fiscal years 1991 to 1995 for this activity.

The Food and Drug Administration (FDA) currently administers fish inspection programs. In fiscal year 1990, FDA plans to spend approximately $16 million on sampling and inspecting fish products. This bill, however, specifies that once the Department of Agriculture's fish inpsection program is fully implemented, three years after the enactment of this bill, the FDA would no longer have authority to conduct fish inspection activities. Therefore, CBO estimates that there would be an offset of approximately $19 million in fiscal year 1994, and $20 million in fiscal year 1995 as a result of this provision.

This estimate assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

6. Estimated cost to State and local government: S. 1245 would allow States to establish their own programs to inspect fish involved in interstate commerce. The Federal Government would require States to pay at least 50 percent of the costs they would incur from conducting such inspections.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Karen Graham.

10. Estimate approved by: C.G. Nuckols, for James L. Blum, Assistant Director for Budget Analysis.

Regulatory Impact Evaluation

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee made the following evaluation of the regulatory impact which would be incurred in carrying out S. 1245.

The bill requires the Department of Agriculture to issue regulations regarding the administration and implementation of a national mandatory fish inspection program which also covers imports. This will be a detailed and extensive rulemaking process and the bill will require a substantial commitment of staff and resources of the Department. The annual costs of this sampling and inspection program are likely to be around $90 million.

The Department of Commerce may issue regulations under this bill regarding water quality issues and the handling of vessels.

The Food and Drug Administration is required to issue tolerances for potentially harmful substances found in fish products capable of use as human food.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by the bill S. 1245, as ordered reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FOOD SECURITY ACT OF 1985

* * * * * * *

TITLE XVIII—GENERAL EFFECTIVE DATE

SEC. 1801. Except as otherwise provided in this Act, this Act and the amendments made by this Act shall become effective on the date of the enactment of this Act.

TITLE XIX—FISH INSPECTION PROGRAM

SEC. 1901. DEFINITIONS.

As used in this title:

(1) ADULTERATED.—The term "adulterated" means any fish product that—

(A) bears or contains any poisonous or deleterious substance that may render such product injurious to health, except that if such substance is a naturally occurring part of the fish product, such product shall not be considered adulterated if the quantity of such substance does not ordinarily render such fish product injurious to human health;

(B)(i) bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical, a food additive, or a color additive) that may, in the judgment of the Secretary, make such product unfit for human food;

(ii) is, in whole or in part, a raw agricultural commodity and such commodity bears or contains any pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a);

(iii) bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 348); or

(iv) bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 376), except that a fish product that is not otherwise considered to be adulterated under this clause or under clauses (ii) or (iii) shall be considered to be adulterated if the use of a pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations promulgated by the Secretary in establishments;

(C) consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthy, unwholesome, or otherwise unfit for human food;

(D) has been prepared, packed, or held under insanitary conditions that may have resulted in such fish product becoming contaminated with filth, or becoming injurious to human health;

(E) is, in whole or in part, derived from any fish product identified as adulterated under the procedures described in section 1903(d);

(F) is or was contained in a container that is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(G) has been intentionally subjected to radiation, except that the use of radiation in compliance with a regulation or exemption in effect under section 409 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 348) shall not make such fish product adulterated under this subparagraph;

(H)(i) has any valuable constituent, in whole or in part, omitted or abstracted therefrom;

(ii) has any substance substituted, wholly or in part therefor;

(iii) has damage or an inferiority concealed in any manner; or

(iv) has substance added thereto or mixed or packed therewith so as to increase the bulk or weight, reduce the quality or strength, or make the appearance of such fish product better or of greater value then it actually is;

(I) has been made or derived in whole or in part from fish harvested in a production area that has been closed under this title, or closed to commercial fishing for that species by any State or other appropriate authority for reasons related to food safety;

(J) has been imported from a country not certified by the Secretary to export to the United States under section 1910(e);

(K) has been processed by any establishment whose facilities or equipment, or the operation thereof, fail to meet the requirements of this title; or

(L) has been handled by an establishment for which a certificate has not been issued, or by an establishment no longer holding a certificate.

(2) CAPABLE OF USE AS HUMAN FOOD.—The term "capable of use as human food" shall apply to any fish product that is capable of being consumed by humans as food, unless it is denatured or otherwise identified as required by regulations promulgated by the Secretary to deter its use as human food, or unless it is naturally inedible by humans.

(3) CERTIFICATE.—The term "certificate" means any certificate, prescribed under regulations promulgated by the Secretary, for issuance by an inspector or other person performing official functions under this title.

(4) COMMERCIAL FISHING VESSEL.—The term "commercial fishing vessel" means a vessel that commercially engages in the catching, taking, or harvesting of fish or any activity that can reasonably be expected to result in the catching, taking, or harvesting of fish, capable of use as human food an intended for human consumption.

(5) CONTAINER, PACKAGE.—The terms "container" and "package" include any box, can, tin, cloth, plastic, or other receptacle, wrapper, or cover.

(6) ESTABLISHMENT.—The term "establishment" means any fish processing vessel that is subject to the jurisdiction of the United States, or any building, premises, structure, or other facility located in any State or Territory that is used in the handling or processing of fish products. Such term shall not include—

(A) recreational vessels, fish tender vessels, commercial fishing vessels, or aquaculture operations, unless any such vessels or operations process fish;

(B) retail stores;'

(C) restaurants; or

(D) contract or common carriers that transport fish products.

(7) FISH.—The term "fish" includes freshwater or marine finfish, mollusks, crustaceans, and other forms of aquatic animal life, including amphibians, whether from wild or cultured sources, other than birds or mammals.

(8) FISH PROCESSING VESSEL.—The term "fish processing vessel" means a vessel that commercially prepares fish products, other than by gutting, decapitating, salting, gilling, skinning, shucking, icing, freezing to the extent that such freezing is associated with other actions related to processing, or brine chilling.

(9) FISH PRODUCT.—the term "fish product" means any food product capable of use as human food derived in whole or in substantial part from fish, including unprocessed fish or any part thereof, excepting products which contain fish ingredients only in a relatively small proportion or that historically have not been considered by consumers as products of the fish food industry, and that are exempt from the definition of fish or fish product by the Secretary under such conditions as the Secretary may prescribe to ensure that the fish ingredients contained in such product are not adulterated and that such products are not represented as a fish product.

(10) FISH TENDER VESSEL.—The term "fish tender vessel" means a vessel that commercially supplies, stores, refrigerates, or transports fish products that are intended for human consumption, or materials directly related to fishing or the preparation of fish, to or from a commercial fishing vessel, fish processing vessel, fish tender vessel or a fish processing facility.

(11) IMMEDIATE CONTAINER.—The term "immediate container" includes any consumer package, or any other container in which fish products, not consumer packaged, are packed.

(12) INSPECTOR.—The term "inspector" means any individual appointed or authorized by the Secretary to make inspections, to

review compliance, or to perform other functions under this title.

(13) INTERSTATE COMMERCE.—The term "interstate commerce" means commerce between any State or Territory, and any place outside thereof, or within any territory not organized with a legislative body.

(14) LABEL.—The term "label", with respect to fish products, means a display of written, printed, or graphic matter appearing on the immediate container (not including package liners) of any fish product.

(15) LABELING.—The term "labeling", with respect to fish products, means all labels and other written, printed, or graphic matter on any fish product or on any of the packages, containers, or wrappers of such article, or accompanying any fish product.

(16) MISBRANDED.—The term "misbranded" means any fish product—

(A) the labeling of which is false or misleading in any manner;

(B) if such fish product is offered for sale under the name of another food;

(C) if the package of such fish product is so made, formed, or filled as to be misleading;

(D) if the label of such fish product is not approved by the Secretary, or is not in a standard form that is approved by the Secretary, or otherwise is not in conformity with regulations promulgated by the Secretary;

(E) if such fish product is an imitation of another food product, unless the label of such fish product bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;

(F) such fish product does not bear a label disclosing—

(i) the name and the place of business of the manufacturer, packer, or distributor; and

(ii) an accurate statement of the quantity of such fish product in terms of weight, measure, or numerical count, except that reasonable variations may be permitted, and exemptions as to small packages or articles that are not in packages or other containers may be established by regulations promulgated by the Secretary;

(G) if any word, statement, or other information required by or under the authority of this title to appear on the label or labeling of such fish product is not prominently placed on such product with such conspicuousness (as compared with other words, statements, designs, or devices, in such labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(H) if such fish product purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations of the Secretary under section 1908 of this title unless—

(i) such fish product conforms to such definition and standard; and

(ii) the label of such product bears the name of the food specified in such definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(I) if such fish product purports to be or is represented as a food for which a standard or standards of fill of the container of such product have been prescribed under regulations promulgated by the Secretary, and such fish product falls below the standard of fill of container that are applicable thereto, unless the label of such product bears, in such manner and form as such regulations require, a statement that it falls below such standard;

(J) if such fish product is not subject to the provisions of subparagraph (H), unless its label bears—

(i) the common or usual name of the food, if any such common or usual name exists; and

(ii) in the case of a product that is fabricated from two or more ingredients, the common or usual name of each such ingredient, except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each and, to the extent that compliance with this clause in impracticable or results in deception or unfair competition, exemptions shall be established through regulations promulgated by the Secretary;

(K) if such fish product bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless the fish product bears a label that states that fact, except that to the extent that compliance with the requirements of this subparagraph are impracticable, exemptions shall be established through regulations promulgated by the Secretary; or

(L) if such fish product fails to bear on its package or immediate container, and in the case of nonconsumer packaged fish (if the Secretary so requires) directly thereon, as the Secretary may through regulations prescribe, the official mark, and such other information as the Secretary may require in such regulations to ensure that such fish product will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

(17) OFFICIAL MARK.—The term "official mark" means any official inspection legend or any other symbol, prescribed under regulations promulgated by the Secretary, to identify the establishment and the status of any fish product under this title.

(18) OWNER OR OPERATOR.—The term "owner or operator" means any person who owns, operates, leases, charters, or otherwise controls in whole or in part any establishment or vessel.

(19) PERSON.—The term "person" means any individual, partnership, corporation, establishment, importer of fish products, association, or other business unit.

(20) PESTICIDE CHEMICAL, OTHER TERMS.—The terms "pesticide chemical", "food additive", "color additive" and "raw ag-

ricultural commodity" shall have the same meanings given such terms under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, et. seq.).

(21) PROCESS.—The terms "process" and "processing", with respect to fish products, means to prepare or manufacture such fish products by canning, cooking, smoking, filleting, fermenting, freezing to the extent that the freezing is associated with other actions related to processing, dehydrating, drying, and consumer packaging.

(22) PROGRAM.—The term "program" means all aspects of the inspection and sampling program for fish products established under this title.

(23) RECREATIONAL VESSEL.—The term "recreational vessel" means a vessel operated primarily for pleasure, or leased, rented or chartered to another for the pleasure of the leasee.

(24) SECRETARY.—The term "Secretary" means the Secretary of Agriculture.

(25) SHIPPING CONTAINER.—The term "shipping container" means any container used or intended for use in packaging a fish product packed in an immediate container.

(26) STATE.—The term "State" means any of the 50 States, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, and American Samona.

(27) TERRITORY.—the term "Territory" means any territory or possession of the United States not included in the definition under paragraph (26).

SEC. 1902. EXEMPTIONS AND EXCLUSIONS.

(a) GENERAL EXEMPTIONS.—The Secretary shall, by regulation and under such conditions as the Secretary may prescribe, exempt from specific provisions of this title—

(1) the processing by any individual of fish products raised or harvested by that individual exclusively for use by that individual or by the members of the household, the nonpaying guests, and the employees of that individual;

(2) the custom processing, in any establishment or vessel, of fish products that the owner of such products will exclusively use, in the household of the owner, for the owner or the members of the household, the nonpaying guests, or the employees of the owner, if—

(A) such establishment or vessel ensures that such fish products are segregated at all times from fish products processed for sale;

(B) such fish products are plainly labeled or marked as "Not for Sale"; and

(C) such establishments and vessels are maintained and operated in a sanitary manner;

(3) any establishment or vessel that processes only fish products that are not intended for use as human food, if such fish products are, prior to their offer for sale or other disposition in commerce, not capable of use as human food.

(4) the entry, or withdrawal from warehouse, for consumption in the United States of any fish product acquired outside the

United States for consumption by the person entering or withdrawing it if—

(A) the total amount of such fish product does not exceed 50 pounds as the Secretary may prescribe by regulation; or

(B) the fish product is exempted by regulation because it was caught for other than commercial purposes in waters outside the United States; and

(5) operations of types traditionally and usually conducted at retail stores or restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities of fish products to consumers at such stores or restaurants.

(b) EXCLUSIONS.—This title shall not apply to recreational vessels, commercial fishing vessels or fish tender vessels except where such vessels process fish.

SEC. 1903. FEDERAL AND STATE COOPERATION.

(a) STATE PROGRAMS.—

(1) POLICY.—It is the policy of Congress to protect the consuming public from fish products that are adulterated or misbranded and to assist in the efforts of State and other government agencies to accomplish this objective.

(2) INTRASTATE INSPECTION PROGRAMS.—

(A) AUTHORITY OF SECRETARY.—

(i) IN GENERAL.—The Secretary may, when the Secretary determines that it would effecutate the purposes of this title cooperate with the appropriate State agency in any State that has enacted a mandatory State fish product inspection law that imposes inspection, sampling, sanitation and other requirements of the type described in this title, that are at least equal to those described in this title, to assist such State in developing and administering a State fish product inspection program with respect to all or certain classes of persons engaged in the State in processing fish products solely for sale or other distribution within such State.

(ii) MARKS OR CERTIFICATES.—Each State program described in clause (i) applicable to fish products in instrastate commerce shall not permit such fish products to bear any official marks or certificates applicable to fish products in interstate commerce as authorized under this title, and any labels on such fish products shall clearly indicate that the fish product is for intrastate commerce only.

(B) ADULTERATION.—Fish products processed or handled for instrastate commerce, as authorized under a program established under subparagraph (A), that are sold, transported, or delvered for introduction into, or offered for sale in interstate commerce shall be considered to be adulaterated for purposes of this title.

(C) WARNING NOTICE.—If the Secretary determines that a State fish product inspection program established under subparagraph (A) is not at least equal to the program established under this title, or that a State has failed to main-

tain or is not enforcing a fish product inspection program at least equal to the program established under this title, the Secretary shall promptly notify the chief executive officer of the State of such determination.

(D) NOTICE.—If, after the notification is provided to a State under subparagraph (C), and after the Secretary has consulted with the State and provided the State with an opportunity to promptly correct any deficiencies identified in such notification, the Secretary determines that a State fish product inspection program continues to have State standards that are not least equal to those established under this title or that the State has failed to maintain or is not enforcing a program having standards at least equal to those established under this title, the Secretary shall—

(i) promptly notify the chief executive officer of such State of such determination;

(ii) discontinue assistance to such State under this title;

(iii) advise the Commissioner of Food Drugs of such determination; and

(iv) notwithstanding any other provision of this title, in the case of adulterated fish products that are being distributed or sold within such State that are determined to clearly endanger the public health, the Secretary shall immediately notify the chief executive officer of the State of such determination, and if the State does not take action to prevent such endangering of the public health within a reasonable period of time after the receipt of such notice, as determined by the Secretary, in light of the risk to public health, the Secretary may require that such State be subject to the provisions of this title as though the fish products were in interstate commerce until such time as the Secretary determines that the State has developed and will enforce requirements at least equal to those imposed under this title.

(3) INTERSTATE COMMERCE.—

(A) AUTHORITY OF THE SECRETARY.—

(i) IN GENERAL.—The Secretary may, when the Secretary determines that it would effectuate the purposes of this title, cooperate with appropriate State agencies concerning the State administration of the inspection and sampling components of the program established under this title on behalf of the Secretary.

(ii) REGULATIONS CONCERNING STATE ADMINISTRATION.—The Secretary shall promugate regulations concerning the State administration of the sampling and inspection components as described in clause (i) on behalf of the Secretary.

(iii) COOPERATION.—The Secretary may cooperate with other agencies of the Federal Government in implementing this title.

(iv) EXAMINATIONS ETC.—In carrying out this title, the Secretary shall conduct such examinations, investi-

gations, and inspections as the Secretary determines practicable through any officer or employee of any State commissioned by the Secretary for such purpose. The Secretary shall monitor, investigate and evaluate each program administered under this paragraph on behalf of the Secretary by a State on an ongoing basis to assure that such programs comply with the regulations and other requirements of the Secretary. The Secretary shall be responsible for the enforcement of this title with respect to States that administer the program on behalf of the Secretary.

(B) FINANCIAL ASSISTANCE.—

(i) AUTHORITY.—The Secretary, in cooperating with State agencies under this paragraph, may provide such State agencies with—

(I) advisory assistance in planning and otherwise developing an adequate State program under this paragraph; and

(II) technical and laboratory assistance and training (including necessary curricular and instructional materials and equipment), and financial and other assistance necessary for the administration of a program under this paragraph.

(ii) AMOUNT.—The amount to be contributed to any State by the Secretary for an approved State interstate commerce sampling and inspection program for any year shall not exceed 50 percent of the total cost of the cooperative program, and Federal funds utilized by the Secretary under such clause shall be allocated among the States desiring to cooperate under this paragraph on an equitable basis. Such cooperation and payment shall be contingent at all times on the demonstration that the State program is adequate to effectuate the sampling and inspection requirements of this title.

(iii) WITHHOLDING OF ASSISTANCE.—The Secretary may promulgate regulations to provide for the withholding of Federal assistance under this subparagraph if the Secretary determines that the State is not effectively and properly administering the State program under this title. Such regulations may provide for the subsequent payment of any withheld assistance if the State, to the satisfaction of the Secretary, corrects any deficiencies determined by the Secretary to exist.

(C) FEDERAL-STATE PARTNERSHIPS.—The Secretary shall establish procedures to enable States to apply to administer, on behalf of the Secretary, an inspection and sampling program under this paragraph.

(D) PLAN OF OPERATION.—Each State approved by the Secretary to administer an inspection and sampling program for the Secretary under this paragraph shall annually prepare and submit to the Secretary a plan of operation that shall contain such information as the Secretary shall by regulation require, including a description of—

(i) the manner in which the State intends to administer the fish product inspection and sampling program consistent with the requirements of this title;

(ii) the State plans for sampling fish products and for inspecting and monitoring establishments;

(iii) State cost projections that contain the anticipated cost to the State in administering the program on behalf of the Secretary;

(iv) the staffing, equipment, and other needs of the State to administer such program and the indicators of the expected performance of the State in the administration of the program;

(v) the types of reports and other information that the State shall provide, as may be required by the Secretary; and

(vi) the procedures that the State will utilize for the issuing and handling of advance Federal payments under this title, and for the financial recordkeeping concerning the Federal share of the total cost of the cooperative programs administered under this paragraph.

(E) STANDARDS FOR FEDERAL-STATE COOPERATION.—

(i) ESTABLISHMENT.—The Secretary shall establish standards for the efficient and effective administration of the sampling and inspection program by each State whose application and plan of operation has been approved under this paragraph.

(ii) WARNING NOTICE.—If the Secretary determines that any State inspection and sampling program established under this paragraph is not at least equal to the program established under regulations promulgated by the Secretary, or that a State has failed to maintain or is not operating a program at least equal to the program established under this title, the Secretary shall promptly notify the chief executive officer of the State of such determination.

(iii) DESIGNATION BY SECRETARY.—If, after issuing a notification under clause (ii) to a State and after consulting with such State and providing an opportunity for the State to promptly correct any deficiencies identified in such notification, the Secretary determines that a State inspection and sampling program operated under this paragraph does not have standards that are at least equal to those required under this title or that such State has failed to maintain or operate a program having standards at least equal to those under this title, the Secretary shall promptly notify the chief executive officer of such State of such determination and designate such State as one in which the Federal inspection program established under this title shall apply.

(F) DEPUTIZATION OF STATE EMPLOYEES.—The Secretary may deputize specific State employees in States approved to administer the Federal inspection and sampling program on behalf of the Secretary under this paragraph, under an

annual agreement with each participating State to carry out, on behalf of the Secretary, the inspection program established under this title.

(4) ADVISORY COMMITTEES.—The Secretary may appoint advisory committees consisting of such representatives of appropriate State agencies as the Secretary and the State agencies may designate to consult with the Secretary concerning State and Federal programs with respect to fish product inspection and other matters within the scope of this title. Such advisory committees may conduct evaluations of State programs and attempt to obtain improved coordination and more uniformity among such State programs and between the Federal and State programs, and shall provide advice on the protection of consumers.

(5) LOCAL COOPERATION.—The appropriate State agency with which the Secretary may cooperate under this subsection shall be a single agency in the State that is primarily responsible for the coordination of the State programs having objectives that are the same as the objectives of this title. If the State program includes performance of certain functions by a municipality or other subordinate governmental unit, such unit shall be considered to be a part of the State agency for purposes of this subsection.

(b) DEVELOPMENT OF FEDERAL INSPECTION PROGRAM.—The Secretary shall develop and administer a comprehensive and efficient health-based inspection program for fish products designed to protect the consuming public from fish products that may be adultered or misbranded.

(c) FEDERAL PROGRAM REQUIREMENTS.—The inspection program established by the Secretary under subsection (b) shall—

(1) be specifically designed to take into consideration the special characteristics of fish species and fish products;

(2) be based on a comprehensive assessment of fish and fish products, and the processing and handling of such products, that identifies the hazards and risks, and that prescribes health-based standards for sanitation in the processing of fish products in establishments to ensure that fish products will not be adulterated or misbranded when delivered to the consumer;

(3) be based on a consideration by the Secretary of all procedures utilized during the processing and distribution of fish including—

(A) the identification and assessment of the severity of the potential health risks associated with fish, fish species, and fish products and with the processing and handling of such fish, species, and products;

(B) a determination of the sources and specific points of potential contamination that may adulterate fish products; and

(C) the potential for persistence and multiplication or concentration of contaminants in fish and fish products;

(4) be based on the need to require procedures to prevent, eliminate or control potential contaminants that may adulterate fish and fish products and the need to monitor those procedures;

(5) be specifically designed to take into consideration the distinctive characteristics, hazards, control points, and processing procedures related to different species of fish;

(6) assure, through frequent, and unannounced or announced, inspections of establishments that the processing of fish products complies with the standards prescribed pursuant to this title and the regulations issued by the Secretary thereunder, including standards for good sanitation, manufacturing, processing, storage, temperature control, packaging, and handling, taking into consideration—

(A) the nature and frequency of operations;

(B) the adequacy of monitoring programs;

(C) the history of compliance with this title;

(D) the recommendations of the Model Seafood Surveillance Program;

(E) the potential of the operations to affect human health based on the probability of fish, fish species, or fish products being susceptible to adulterants or otherwise having potential to affect public health;

(F) the compliance of the establishment with other federal health and safety laws; and

(G) such other factors as the Secretary may determine appropriate;

(7) not require the freezing or cooking of fish or fish products that are intended for raw consumption unless the Secretary determines that such freezing or cooking is the only practical procedure available that will adequately prevent, eliminate, or control an identified source of adulteration in the specified fish species;

(8) provide for the identification and classification of fish growing and harvesting areas in conjunction with the appropriate Federal and State agencies;

(9) provide for the delegation, as described in this title, of certain inspection and sampling authorities to State governments and provide compensation to the States for carrying out such authority at a level not to exceed 50 percent of the total cost of the cooperative program;

(10) provide for the sampling and inspection of fish products, and for the monitoring, and the taking of samples or readings, at such points, in such manner, and with such frequency as the Secretary determines necessary, taking into consideration the factors described in subparagraphs (A) through (G) of paragraph (6);

(11) establish procedures (that may include requiring the marking of containers, packages or fish products, or by requiring such recordkeeping, lot processing, or other handling procedures as the Secretary determines appropriate) to assist the Secretary in determining sources of contamination, including determining which harvesting or growing areas are likely to produce fish that are adulterated; and

(12) provide for the promulgation of regulations establishing rules for the identification, naming, labeling and fill of containers of fish products taking into consideration current industry practices and Federal regulations.

(d) TOLERANCES.—

(1) POISONOUS OR DELETERIOUS SUBSTANCES.—

(A) IN GENERAL.—The Commissioner of Food and Drugs shall establish tolerances, except where such tolerances are established by the Administrator of the Environmental Protection Agency, that shall be applicable to poisonous or deleterious substances that may adulterate fish products under the definition of adulteration contained in subpargraphs (A) and (B) of section 1901(1), which shall be used by the Secretary to determine instances in which fish products will be considered adulterated under such subparagraphs. Any such tolerances shall be established at levels so that fish products are not injurious to health.

(B) CONSULTATION.—Tolerances shall be established under subparagraph (A) in consultation with—

(i) the National Academy of Sciences;

(ii) the Environmental Protection Agency;

(iii) the Centers for Disease Control;

(iv) the Secretary of Agriculture;

(v) the Secretary of Commerce; and

(vi) the Interstate Shellfish Sanitation Conference.

(C) BASIS.—Tolerances shall be established under subparagraph (A) based on a scientific analysis of the health risks attributable to the poisonous or deleterious substance for which the tolerance is being established.

(D) TRADE REPRESENTATIVES.—The Commissioner of Food and Drugs shall consult and advise the United States Trade Representative concerning tolerances that may apply to international trade negotiations.

(E) RECONSIDERATION.—The Commissioner of Food and Drugs or the Administrator of the Environmental Protection Agency shall review and reconsider any tolerances established under subparagraph (A) concerning fish products as new scientific information or new technologies become available.

(2) CONTAMINANTS.—The Commissioner of Food and Drugs shall establish tolerances, except where such tolerances are established by the Administrator of the Environmental Protection Agency under the Federal Food, Drug and Cosmetic Act, for harmful chemicals, toxins, parasites, pathogenic microorganisms, viruses, bacteria, and other harmful agents, that may render fish products adulterated.

(3) INDICATORS.—The establishment of tolerances under this subsection may include the use of indicators present in fish or fish products, including indicator organisms, from which it may reasonably be inferred that a hazardous or injurious contaminant or substance is present whenever the contaminant or a poisonous or deleterious substance itself cannot be cost-effectively detected.

SEC. 1904. GROWING AND HARVESTING AREAS.

(a) IDENTIFICATION OF GROWING AREAS.—The Secretary of Commerce for waters under the exclusive jurisdiction of such Secretary, and appropriate State authorities for waters under the jurisdiction

of such appropriate State authorities, shall establish a system for the identification and classification of growing and harvesting areas for fish in coastal areas and the Great Lakes.

(b) MONITORING.—The Secretary shall sample and test fish products to determine if there is any significant instance or trend in the condition of such fish products that may pose a significant threat to the health and safety of consumers.

(c) NOTICE.—

(1) DETERMINATION.—If the Secretary determines that a significant instance or trend of the type described under subsection (b) exists, the Secretary shall notify the appropriate State or Federal agencies with authority to remedy such instance or trend. Such agencies shall include—

(A) the Interstate Shellfish Sanitation Conference;

(B) the State from which any such fish may have been harvested;

(C) the Secretary of Commerce;

(D) the Commissioner of Food and Drugs; and

(E) the Administrator of the Environmental Protection Agency.

The Secretary shall publish notice of the significant instance or trends determined to exist in the Federal Register.

(2) ACTIONS.—Each agency notified under paragraph (1) shall, not later than 30 days after the receipt of such notice, inform the Secretary in writing of any actions that such agency has taken to prevent the distribution of adulterated fish products to consumers. Any such written information shall be available for public inspection.

(d) GRANTS.—The Secretary, in cooperation with States under this section, may provide States with financial and other assistance to prevent the entry of adulterated fish products into establishments, including annual grants to each State that is a member of the Interstate Shellfish Sanitation Conference.

(e) CLOSURE OF AREAS.—

(1) IN GENERAL.—In the case of public health emergencies or on receiving notice of the type described in subsection (b) from the Secretary, the Secretary of Commerce may close waters under the exclusive jurisdiction of the Secretary of Commerce, or otherwise restrict the harvesting of a fish species in such waters if the Secretary of Commerce determines that fish of such species within the identified harvesting or growing areas are likely to be adulterated.

(2) REVIEW.—The Secretary of Commerce shall periodically review the growing and harvesting areas closed or restricted under this subsection to determine whether such closure or restriction should be removed. The Secretary of Commerce shall establish procedures to permit further review on petitions by affected persons.

(3) NOTICE.—The Secretary of Commerce shall give reasonable public notice, except in cases determined to be public health emergencies, prior to ordering any closure or restriction under this section.

SEC. 1905. POWER OF INSPECTORS.

(a) ACTIONS OF INSPECTORS.—Inspectors authorized by the Secretary to conduct inspections, enforce compliance, and otherwise implement his title (including State employees so authorized) shall, pursuant to procedures prescribed by the Secretary, take such actions as are necessary in the judgment of the inspector to implement this title and the regulations promulgated under this title. Such actions may include—

(1) the inspection of establishments and all locations within establishments, including fish products, packages, containers, labeling, equipment, processing procedures, and records related to this title;

(2) the sampling and testing of fish products;

(3) the detention and condemnation of adulterated or misbranded fish products in accordance with this title; and

(4) the inspection, sampling and testing of imports of fish products.

(b) CONDEMNED FISH PRODUCTS.—

(1) IN GENERAL.—Except as provided in paragraph (2), all fish products found by the Secretary to be adulterated or misbranded shall be immediately segregated, seized, and, if objection is not made within 48 hours, condemned. If objection is made, such fish products that are in perishable form may be processed to the extent necessary to prevent spoilage pending hearing and judicial review.

(2) COMPLIANCE ACTIONS.—If the Secretary determines that an adulterated or misbranded fish product can, by relabeling or other action, be brought into compliance with this title or the regulations promulgated under this title, the Secretary may defer a final determination as to the condemnation of such fish product pending the performance by the applicant within a time period specified by the Secretary of such relabeling or other action as the Secretary may authorize. If after such action is performed, the Secretary determines that the fish product has been brought into compliance with this title, the Secretary shall permit its entry into commerce.

(3) DESTRUCTION.—A fish product condemned by the Secretary without objection, or after hearing and judicial review under section 1918, shall be destroyed and not utilized for human food purposes under the supervision of the Secretary.

(c) ACCESS.—Inspectors under this title shall have access, for purposes of examination, sampling, inspection, condemnation, and for such other purposes as are determined necessary, to every part of any establishment.

SEC. 1906. SANITARY CONDITIONS.

(a) MAINTENANCE OF FACILITIES.—Each establishment shall maintain premises, facilities, and equipment, and the operation of such, in accordance with such sanitary practices as are required under regulations promulgated by the Secretary for the purpose of preventing the entry into, or flow or movement in, or burdensome effect on, commerce, of fish products which are adulterated.

(b) STORAGE OR HANDLING.—The Secretary shall, by regulation, prescribe conditions under which fish products shall be stored or

otherwise handled by any person engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, such articles, when the Secretary determines that such action is necessary to ensure that such articles will not be adulterated or misbranded when delivered to the consumer. The Secretary may establish guidelines for the training of persons who are employed by establishments involved in fish and fish product sanitation and quality control.

(c) TEMPORARY EXEMPTION AUTHORITY.—The Secretary may, under such sanitary conditions as the Secretary may by regulation prescribe, exempt from the inspection requirements of this title until, July 1, 1995, or earlier, the handling or processing of fish products by any person, where the Secretary determines—

(1) that it is impractical to provide such inspection based on the amount of funds appropriated for the administration of this title; and

(2) that an exemption under this subsection will aid in the effective transition to the program implemented under this title.

SEC. 1907. CERTIFICATION OF ESTABLISHMENTS, IMPORTERS.

(a) IN GENERAL.—

(1) PROCEDURES.—The Secretary shall establish procedures for the annual certification, or decertification for good cause, of establishments, and persons engaged in the business of importing of fish or fish products.

(2) INFORMATION.—The Secretary shall require such information as the Secretary determines appropriate for application for certification under paragraph (1), including the name of the owner and operator of the establishment or import business, the principal place of business, and a list of each type of fish or fish product typically processed, handled, or imported by each such establishment or importer.

(3) PROHIBITION.—No establishment or person engaged in the business of importing shall process or handle any fish product for commercial purposes unless such establishment or importer is certified by the Secretary.

(b) APPLICATIONS.—Applications for certification under subsection (a) shall be made to the Secretary using such forms and requiring such information as the Secretary shall prescribe by regulation including a description of the quality control program of the establishment or importer.

(c) REFUSAL TO CERTIFY, REVOCATION.—

(1) IN GENERAL.—If an establishment or importer certified under subsection (a) fails to comply with any requirement of this title or the regulations promulgated under this title, the Secretary may, after notice and an opportunity for a hearing—

(A) revoke such certification;

(B) suspend such certification for a period of time; or

(C) impose conditions or restrictions on such certification as the Secretary determines necessary and appropriate.

(2) DENIAL OR REVOCATION.—The Secretary may (for such period, or indefinitely, as the Secretary determines necessary to effect the purposes of this title) refuse to certify or decertify an establishment or importer if the Secretary determines, after pro-

viding such establishment or importer with an opportunity for a hearing, that such establishment or importer is unfit to engage in any business subject to or requiring inspection under this title as a result of the establishment or importer, or anyone responsibly connected with the establishment or importer, having been convicted in any Federal or State court of—

(A) acquiring, handling, or distributing adulterated, mislabeled, or deceptively packaged food or fraud in connection with transactions in food; or

(B) any felony, involving fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health.

(3) RESPONSIBLY CONNECTED.—For the purpose of this subsection a person shall be considered to be responsibly connected with the establishment or importer if such person is a partner, officer, director, holder, or owner of 10 percent or more of the voting stock of the establishment or importer or is an employee in a managerial or executive capacity, as defined in regulations promulgated by the Secretary.

(4) HEARINGS.—On the revocation of a certification for failure to destroy condemned fish products as required under this title, or as a result of any other failure of an establishment or importer to comply with the requirements of this title as to premises, facilities, or equipment, or the operation thereof, or other noncompliance with the requirements of this title, the applicant for, or holder of, the certification shall, on request, be afforded an opportunity for a hearing with respect to the merits or validity of such action under section 1918. Such decertification or refusal to certify shall continue in effect unless otherwise ordered by the Secretary.

(5) REINSTATEMENT.—

(A) IN GENERAL.—An establishment or importer that has had a certification revoked or suspended under this subsection may apply for reinstatement of such certification. The Secretary shall grant such reinstatement, if the revocation or suspension is pending in a hearing or appeal under paragraph (4), if the Secretary determines that the establishment or importer is fit to engage in the handling or processing of fish products.

(B) CONDITIONAL OR RESTRICTED CERTIFICATIONS.—An establishment or importer that has a certification that is conditional or restricted may apply for the removal of such conditions or restrictions. The Secretary shall immediately remove such conditions or restrictions, if the existence of the condition or restriction is pending in a hearing or appeal under paragraph (4), if the Secretary finds that adequate measures have been taken to comply with this title or regulations promulgated under this title.

SEC. 1908. LABELING, PACKAGING AND MARKING.

(a) LABELING.—All fish products processed at any establishment certified under this title, and that are not found to be adulterated, shall at the time that such products leave the establishment bear, in

distinctly legible form, on their shipping containers and immediate containers such information as the Secretary may require. The Secretary may permit such fish products to bear a seal stating that the product was processed in accordance with Federal standards or such similar language as the Secretary determines appropriate.

(b) PROTECTION OF PUBLIC.—The Secretary, when the Secretary determines such action is necessary for the protection of the public, may prescribe—

(1) the styles and sizes of type to be used, with respect to material required to be incorporated in labeling to avoid false or misleading labeling, in marking and labeling any fish products subject to this title;

(2) definitions and standards of identity or composition of articles subject to this title and standards of fill of containers for such articles that shall not be inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act; and

(3) procedures that permit statements on labels that indicate the State or location of origin of the product.

(c) MARKING.—The Secretary shall—

(1) require the owner or operator of any establishment certified under this title, to cause each package of fish product that is processed in such establishment to be marked at the time the package leaves the establishment with—

(A) the appropriate identification issued under the authority of this title; and

(B) labeling that bears or contains an official mark; and

(2) ensure that the official mark shall be available only for fish products that are processed in establishments certified under this title.

(d) NO SALES.—No article subject to this title shall be sold or offered for sale in commerce by any person, under any name or other marking or labeling that is false or misleading, or in any container of a misleading form or size. Established trade names and other marking and labeling that are not false or misleading and that are approved by the Secretary are permitted.

(e) FALSE LABELS OR MARKINGS.—

(1) WITHHOLDING REQUIREMENT.—If the Secretary has reason to believe that any marking or labeling or the size or form of any container in use or proposed for use with respect to any article subject to this title is false or misleading in any particular, the Secretary may require that such use be withheld unless the marking, labeling, or container is modified in such manner as the Secretary may prescribe so that it will not be false or misleading.

(2) REQUEST FOR HEARING.—If a person using or proposing to use markings, labeling, or a container that is subject to a withholding requirement under paragraph (1) does not accept such requirement, such person may request a hearing, and the use of such marking, labeling, or container shall, if the Secretary so requires, be withheld pending such hearing and final determination by the Secretary.

(3) APPEALS.—Any determination by the Secretary under paragraph (2) shall be conclusive unless, not later than 30 days

after the person receives notice of such final determination, such person appeals such determination to the United States Court of Appeals for the circuit in which such person has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. The provisions of section 204 of the Packers and Stockyards Act, 1921 (7 U.S.C. 194) shall be applicable to appeals brought under this section.

SEC. 1909. RECORDS, REPORTS AND DISCLOSURE.

(a) IN GENERAL.—Establishments shall maintain accurate records as determined to be appropriate by the Secretary. Any requirements imposed under this section may include information concerning—

(1) the receipt, delivery, sale, movement, or disposition of fish or fish products;

(2) matters reasonably related to whether fish products may be adulterated or misbranded, including the growing or harvesting area from which such fish was harvested;

(3) the effective enforcement of this title to ensure against the sale or distribution of adulterated or misbranded fish products to consumers; and

(4) other activities and matters relevant to food safety and sanitation.

(b) TIME PERIODS.—The persons described in subsection (c) shall, for such period of time as the Secretary may by regulation prescribe (not to exceed 2 years unless otherwise directed by the Secretary for good cause shown) keep and maintain such records as determined by the Secretary to be appropriate under subsection (a).

(c) PERSONS AFFECTED.—The recordkeeping and other requirements of this section shall apply to any person, not exempted under section 1902—

(1) that engages in the business of processing any fish product for interstate commerce; and

(2) that engages in the business of buying or selling (such as acting as products brokers or wholesalers), or transporting, in interstate commerce, or storing in or for interstate commerce or importing any fish products.

(d) ACCESS TO RECORDS.—The Secretary and the Secretary of Commerce shall, on request at reasonable times, have access to and make copies of records maintained under this section.

SEC. 1910. IMPORTS.

(a) REQUIREMENT.—

(1) IN GENERAL.—No fish product shall be entered, or withdrawn from warehouses, for consumption in the United States, unless such fish product—

(A) is not adulterated or misbranded;

(B) complies with all requirements applicable to fish products in commerce in the United States under this title;

(C) is marked and labeled as required by regulations for imported articles; and

(D) complies with the requirements of this title and regulations promulgated under this title.

(2) TREATMENT.—On entry into the United States, any fish product that satisfies the requirements of paragraph (1) shall be considered and treated as domestic fish products under this

title, except that all labeling of such fish products shall identify the country of origin.

(b) INSPECTION OF IMPORTS.—The Secretary shall enforce the requirements of this section through inspections and other procedures, and the sampling and inspection of fish products that are offered for importation or entered, or withdrawn from warehouses, for consumption in the United States, and through any other procedures that the Secretary determines necessary to ensure compliance with this title.

(c) CORRECTIVE ACTIONS.—All fish products that are refused entry into commerce in the United States under subsection (a) or that are entered, or withdrawn from warehouses, for consumption in the United States in violation of this section, shall pursuant to regulations promulgated by the Secretary, be destroyed unless—

(1) such fish products are exported within a time fixed for such exportation by the Secretary; or

(2) the Secretary determines that such fish product can be brought into compliance with this title through relabeling or other action.

If the Secretary makes a positive determination under paragraph (2), the destruction of such fish product may be deferred pending the filing of a written application by the owner or consignee and the execution by the applicant of a bond within a time period specified by the Secretary. On such filing and execution of a bond, the Secretary may authorize the applicant to perform such relabeling or other actions required by the Secretary. If after such action is performed, the Secretary determines that such fish product has been brought into compliance with this title, the Secretary shall permit its entry into commerce.

(d) COSTS.—Storage, cartage, labor, and other costs resulting from the denial of entry, or withdrawal from warehouse, of any fish product under this section shall be paid by the owner or consignee of such product. The nonpayment of such costs shall constitute a lien against such product and any other fish product thereafter entered, or withdrawn from warehouse, for consumption in the United States by such owner or consignee.

(e) FOREIGN SEAFOOD INSPECTION PROGRAM.—

(1) REVIEW.—On request of a country desiring to export fish products to the United States, the Secretary shall review the inspection program, including the sanitary, wholesomeness, quality, species verification, residue and other requirements and tolerances, with respect to fish products to be offered for importation into the United States, to determine whether such requirements and tolerances for such products are at least equal to those established under this title.

(2) CERTIFICATION.—If the Secretary determines that a country desiring to export fish products to the United States meets the standards and procedures set forth in paragraph (1), with respect to fish products to be offered for importation into the United States, and that such country will permit the enforcement measures that the Secretary determines necessary pursuant to paragraph (5), the Secretary shall issue a certificate to such country stating that the country meets such requirements.

(3) EFFECT OF NONCERTIFICATION.—No fish product shall be permitted entry into the United States from a country that does not have such a current, valid certificate issued under this subsection.

(4) REVIEW.—

(A) IN GENERAL.—The Secretary shall periodically review certificates issued under this subsection and shall revoke any such certificate if the Secretary determines that such action is necessary.

(B) INSPECTION.—The consideration of any application for a certification under this subsection and the review of any such certification, by the Secretary, shall include the inspection of individual establishments that produce fish products to be offered for export to the United States to ensure that such products, and the procedures and standards used in handling and processing such products, meet the inspection, sanitary, quality, species verification, residue and other standards and tolerances required by this title.

(5) ENFORCEMENT.—The Secretary shall enforce the requirements of this section through inspections, sampling, testing, or such other actions at such stages in the handling or processing of fish products, whether in the foreign country, during importation, or otherwise as the Secretary determines necessary to ensure compliance with this title.

(f) REPORTS TO CONGRESS.—Not later than March 1 of each year, the Secretary shall submit, to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition and Forestry of the Senate, a comprehensive and detailed written report with respect to the administration of this section during the immediately preceding calendar year. Such report shall include—

(1) a certification by the Secretary that foreign entities exporting fish products under this section have complied with requirements at least equal to all the inspection, building construction standards, and all other provisions of this title and regulations issued thereunder;

(2) the names and locations of establishments authorized or permitted to have imported fish products into the United States;

(3) the number of inspectors employed by the Department of Agriculture in the calendar year for which the report is being prepared that were assigned to inspect the establishments referred to in paragraph (2) and the frequency with which each such establishment was inspected by such inspectors;

(4) the number of inspectors licensed by each country from which any imports subject to the provisions of this section were imported who were assigned, during the calendar year concerned, to inspect such imports and the facilities in which such imports were handled and the frequency and effectiveness of such inspections;

(5) the total volume of fish products that were imported into the United States during the year for which such report was prepared from each country, including a separate itemization of

the volume of each major category of such imports from each country during such year, and a detailed report of rejections of entities for certification and products because of the failure of such entities or products to meet appropriate standards prescribed under this section; and

(6) the name of each foreign country that applies requirements for the importation of fish products from the United States.

(g) RECIPROCAL FISH PRODUCTS INSPECTION REQUIREMENT.—

(1) DETERMINATION.—On request of the Committee on Agriculture or the Committee on Ways and Means of the House of Representatives or the Committee on Agriculture, Nutrition, and Forestry of the Senate, or at the initiative of the Secretary, the Secretary shall, as soon as practicable, determine whether a particular foreign country applies requirements for the importation of fish products from the United States that are not related to public health concerns about end-product quality that can be substantiated by reliable analytical methods.

(2) ACTIONS.—If the Secretary determines that a foreign country applies requirements described in paragraph (1)—

(A) the Secretary shall consult with the United States Trade Representative; and

(B) not later than 30 days after the determination of the Secretary under paragraph (1), the Secretary and the United States Trade Representative shall recommend to the President whether action should be taken under paragraph (3).

(3) PROHIBITION OF IMPORTS.—Not later than 30 days after receiving a recommendation for action under paragraph (2), the President shall, if and for such time as the President determines appropriate, prohibit imports into the United States of any fish products produced in such foreign country unless it is determined that the fish products produced in that country meet the requirements applicable to fish products in commerce within the United States.

(4) ACTION UNDER OTHER LAW.—The action authorized under paragraph (3) may be used in lieu of, or in addition to, any other action taken under any other law.

SEC. 1911. EXPORTS.

(a) STANDARDS.—Fish products intended for export to a foreign country shall not be considered to be adulterated or misbranded under this title if such products—

(1) are exported consistent with the specifications of the foreign purchaser;

(2) are not in conflict with the laws of the country to which they are intended for export;

(3) are labeled on the outside of the shipping package that they are intended for export; and

(4) are not sold, offered for sale, or otherwise disposed of in commerce within the United States except that such fish product shall be considered to be adulterated if the Secretary determines such products represent a threat to the health of the eventual consumer.

(b) INSPECTION.—The Secretary shall inspect fish products intended to be exported to foreign countries at such times and places and in such manner as the Secretary determines necessary.

(c) CERTIFICATES.—The Secretary shall, on request of the exporter, provide a certificate for export stating the condition of fish products inspected under this section.

SEC. 1912. RECALL.

The Secretary may require any person who owns or operates an establishment or is in the business of importing of fish products, to recall any fish product that is adulterated or misbranded if the Secretary determines that such fish product is adulterated or misbranded and could cause serious health consequences.

SEC. 1913. COOPERATION WITH CENTERS FOR DISEASE CONTROL.

The Secretary of Health and Human Services shall establish, through the Centers for Disease Control, an active surveillance system, based on a representative proportion of the population of the United States, to provide an accurate estimate of the frequency of human disease in the United States associated with the consumption of food, including a comparison of each major food category.

SEC. 1914. PROHIBITED ACTS.

The following acts and the causing thereof are prohibited under this title—

(1) the processing or handling of any fish product at any establishment except in compliance with the requirements of this title;

(2) the refusal to permit entry or inspection to or on any establishment or business engaged in importing fish products, or to otherwise interfere with any inspector or other person in carrying out the duties required under this title or under regulations implementing this title;

(3) the sale, transportation, or offer for sale or transportation, in interstate commerce of any fish product that is adulterated or misbranded at the time of such sale, transportation, or offer for sale or transportation;

(4) the possession by any establishment of fish products except in compliance with the requirements of this title or regulations issued under this title;

(5) the commission of any act, or the omission of any act, while fish product is being transported in interstate commerce, or held for sale after such transportation, that is intended to cause or has the effect of causing such products to be adulterated or misbranded;

(6) the sale, transportation, or offer for sale or transportation, in interstate commerce of any fish product that is not processed in accordance with the requirements of this title or any regulations promulgated under this title;

(7) the reproduction, alteration, or destruction of any official stamp or certificate without the authorization of the Secretary;

(8) the misbranding of fish products, or the creation or maintenance of records that are false either by content or omission, or destruction of records containing information required under this title or the alteration or removal of the whole or any part

of the labeling of, or the doing of any other act with respect to fish products if such act is done while such fish products are held for sale (whether or not such sale is the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded;

(9) the handling or processing for interstate commerce of fish products in any establishment unless there is in effect for such establishment a certification issued by the Secretary; and

(10) the importation into the United States of fish products if such articles are adulterated, labeled or packaged in a false or misleading way, or otherwise misbranded, or fail to comply with all the inspection, good processing practices, and other provisions of this title and regulations issued under this title applicable to such articles in interstate commerce within the United States.

SEC. 1915. CIVIL PENALTIES.

(a) FINES.—

(1) IN GENERAL.—Any person who violates any provision of this title, or the regulations promulgated pursuant to this title, shall be liable to the United States for a civil penalty in an amount not to exceed $5,000 for the first violation, increased by 10 percent for each such subsequent violation. Each day of a continuing violation shall constitute a separate offense.

(2) CIVIL ACTIONS FILED IN DISTRICT COURT.—The Secretary may commence a civil action in the United States district court in which the person subject to requirements of this title resides, to seek a civil fine from any such person for violation of this title.

(3) FINDING OF FAILURE TO COMPLY.—If the court, in an action brought under paragraph (2), finds on the basis of clear and convincing evidence, that the person subject to the requirements of this title has failed to comply with such requirements, or the rules and regulations promulgated thereunder, the court shall fine the person not more than $5,000 for each such violation and shall increase such fine by 10 percent for each subsequent violation.

(4) NOTICE.—Not less than 90 days, and not more than 180 days, prior to commencing a civil action under paragraph (2), the Secretary shall provide to each person that is the subject of the action, a written notice that shall include—

(A) a statement that the Secretary intends to commence such an action;

(B) a comprehensive description of the alleged violations of this title and the regulations promulgated under this title; and

(C) a description of the actions to be taken by such person that the Secretary considers necessary to enable the person to comply with this title and to eliminate the need to commence such civil action.

(5) OPPORTUNITY TO BE HEARD.—Prior to the commencement of a civil action by the Secretary under paragraph (2), the Secretary shall provide the person with an opportunity to present,

orally or in writing, information concerning the alleged violations or with respect to such proceeding.

(6) WRITTEN NOTICE OF WARNING.—In determining whether the public interest would be adequately served by issuing a written notice of warning in lieu of commencing a civil action under paragraph (2), the Secretary shall take into account—

(A) the compliance history of the person;

(B) the magnitude of the violations by the person;

(C) whether compliance with this title would be obtained as a result of a notice of warning; and

(D) whether such violation is of a minor or technical nature.

Prior to commencing any such civil action under paragraph (2), the Secretary, after considering the the factors described in subparagraphs (A) through (D), shall provide a written explanation to the establishment concerning the reasons why the alleged violations of the person warrant commencing a civil action.

(b) MODIFICATION.—The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty that is subject to imposition or that has been imposed under this section.

SEC. 1916. CRIMINAL PENALTIES.

(a) IN GENERAL.—Any person who intentionally violates any provision of section 1903, 1908, 1910 or 1914, or the regulations promulgated thereunder, may—

(1) be fined in an amount not to exceed $10,000, or imprisoned for not more than 1 year, or both; and

(2) if such intentional violation involves the intent to defraud, or any distribution of any fish product that is adulterated or misbranded, be fined in an amount not to exceed $20,000, or imprisoned for not more than 3 years, or both.

(b) NOTICE OF WARNING.—In the case of one or more minor violations of this title or the regulations promulgated under this title, the Secretary may, when the Secretary determines that the public interest will be adequately served thereby, issue to the person committing such violation a suitable written notice of warning. In determining whether the public interest will be adequately served by a written notice of warning, the Secretary shall consider, among other factors—

(1) the compliance history of such person;

(2) the magnitude of the violation;

(3) whether compliance with this title would likely be obtained as a result of such notice; and

(4) whether such violation is of a minor or technical nature.

(c) NOTICE TO ALLEGED VIOLATOR.—

(1) IN GENERAL.—Before any violation under this title is reported by the Secretary to any United States attorney for institution of a criminal proceeding under this section, the person against whom such proceeding is contemplated shall be given reasonable notice of the alleged violation and an opportunity to present the views of such person orally or in writing with regard to such contemplated proceeding.

(2) EXCEPTION.—Paragraph (1) shall not apply in those cases where it is determined that such notice would significantly

interfere with the ability of the United States attorney to prosecute any violation. Nothing in this title shall be construed as requiring the Secretary to report for criminal prosecution violations of this title when the Secretary believes that the public interest will be adequately served by the procedures described in subsection (b).

(d) PUBLICATION.—In each case in which a criminal penalty is imposed under this section, the Secretary shall publish the name of the offending person, the location of the violator, the amount of the fine and the reason for the fine.

SEC. 1917. CARRIERS.

No common carrier or contract carrier, including such carriers that are fish tender vessels, shall be subject to penalties under this title for the receipt, carriage, holding, or delivery, in the usual course of business, as a carrier, of any adulterated or misbranded fish product owned by another person, unless the carrier—

(1) during the time of such receipt, carriage, holding, or delivery, had knowledge or was in possession of facts that would cause a reasonable person to believe that the fish products were adulterated or misbranded or were otherwise not eligible for transportation under this title; or

(2) refuses to furnish on request of the Secretary the name and address of the person from whom the carrier received the adulterated or misbranded fish product, and copies of all documents pertaining to the delivery of such fish product.

SEC. 1918. HEARINGS AND SUBPOENAS.

(a) ADMINISTRATIVE HEARINGS.—Except in the case of criminal prosecutions under section 1916, and as described in section 1908(e) and 1915, the Secretary shall afford an opportunity for an administrative hearing, under procedures established by the Secretary through regulations, to any person claiming to be adversely affected by the action or inaction of the Secretary under this title (hereinafter referred to in this section as the "claimant"). Such procedures shall include an opportunity to present evidence, a right of cross examination, and a right to be heard in person or by counsel and through witnesses. After the expiration of 60 days after the entry of an order by the Secretary against the claimant under this section, the Secretary shall take any appropriate action under such order, unless the claimant files for judicial review under subsection (d).

(b) SUBPOENAS.—

(1) AUTHORITY.—For the purposes of any hearing or investigation under this title, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of any documentation or other evidence that relates to any matter under investigation or in dispute before the Secretary and to administer oaths or affirmations.

(2) COMPENSATION.—The Secretary shall pay witnesses subpoenaed under this subsection customary reasonable fees and transportation expenses.

(c) INTERIM RELIEF.—The Secretary may take any actions in emergency situations determined necessary, during the pendency of the administrative hearing process and during the pendency of judicial review (unless the court shall order otherwise) to protect the public

health, curb persistent violations that endanger public health, or enforce other provisions of this title or regulations promulgated pursuant to this title.

(d) JUDICIAL REVIEW.—

(1) PETITION.—Not later than 60 days after the entry of an order by the Secretary, a person adversely affected by such order may obtain judicial review through the filing of a petition of judicial review in the United States court of appeals for the circuit in which such person resides or where the principal place of business of such person is located, by filing with the clerk of such court a written petition praying that the order of the Secretary be set aside or modified in the manner stated in the petition together with a bond in such sum as the court may consider appropriate. A copy of the petition shall be transmitted by the clerk to the office of the Secretary, and the Secretary shall file in the court the record of the proceeding.

(2) EVIDENCE.—The evidence contained in the record of the proceeding filed by the Secretary under paragraph (1) shall be considered by the court as evidence in the case. Judicial review of any such order shall be on the record on which the determination and order are based.

(3) FINDINGS.—The findings of the Secretary concerning questions of fact surrounding the order for which a petition for judicial review is filed shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) ACTION BY COURT.—The court may affirm, modify, or set aside the order of the Secretary. If the court determines that just and proper disposition of the case requires the taking of additional evidence, the court shall order the hearing to be reopened for the taking of such evidence in such manner and on such terms and conditions as the court determines to be appropriate. The Secretary may modify the findings of the Secretary as to the facts or make new findings by reason of the additional evidence so taken, and the Secretary shall file such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the order of the Secretary, with the return of such additional evidence.

(5) APPEAL.—The judgment of the court affirming or setting aside, in whole or in part, any order by the Secretary under this subsection shall be final and subject only to review by the Supreme Court of the United States on certiorari or certification as provided for in section 1254 of title 28 of the United States Code.

SEC. 1919. OTHER CRIMES.

(a) BRIBES.—

(1) PERSON WHO BRIBES.—Any person, or agent or employee of any person, who shall give, pay, or offer, directly or indirectly, to any inspector, or other officer or employee of the United States or a State, authorized to perform any of the duties authorized under this title or under rules or regulations of the Secretary promulgated under this title, any money or other thing of value, with the intent to influence such inspector, officer or employee, in the discharge of any duty of such inspector,

officer or employee provided for under this title, shall be considered to have committed a felony and, on a conviction thereof, shall be punished by a fine not less than $5,000 nor more than $10,000 and by imprisonment for not less than 1 year nor more than 3 years.

(2) PERSON ACCEPTING BRIBES.—Any inspector, officer or employee of the United States or a State authorized to perform any of the duties authorized under this title or under rules or regulations of the Secretary promulgated under this title, who shall accept any money, gift, or other thing of value from any person, or officers, agents, or employees thereof, given with the intent to influence the official action of such inspector, officer, or employee, or who shall receive or accept from any person engaged in commerce any gift, money, or other thing of value given with any purpose or intent whatsoever, shall be considered to have committed a felony and shall, on a conviction thereof, be summarily discharged from office and shall be punished by a fine not less than $1,000 nor more than $10,000 and by imprisonment not less than 1 year nor more than 3 years.

(b) ASSAULT.—Any person who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any inspector or other person while engaged in or on account of the performance of the official duties of such inspector or other person under this title shall be fined not more than $5,000 or imprisoned not more than 3 years, or both. Whoever, in the commission of any such acts, uses a deadly or dangerous weapon, shall be fined not more than $10,000 or imprisoned not more than 10 years, or both. Whoever kills any person while engaged in or on account of the performance of the official duties of such person under this title shall be punished as provided under sections 1111 and 1114 of title 18, United States Code.

SEC. 1920. REGULATION OF PRODUCTS AND ESTABLISHMENTS.

(a) PROCESSING.—Each establishment or import business that is subject to inspection under this title shall be operated in accordance with such sanitary, good processing, quality control, and handling procedures or practices as are required by regulations promulgated by the Secretary.

(b) STAMP.—The Secretary shall by regulation prescribe standards for identifying and otherwise marking fish or fish products, or their packages or containers, with an official stamp. The Secretary shall ensure that the official stamp is available only for fish and fish products that are processed or handled in accordance with the requirements of this title.

(c) RECORDKEEPING.—The Secretary shall promulgate regulations providing for the preparation and maintenance of records that specifically describe all activities relevant to food safety and sanitation. Any such records shall be maintained for such periods of time as the Secretary may by regulation prescribe, but such period shall not exceed 2 years unless the Secretary directs otherwise for good cause shown. Any duly authorized representative of the Secretary shall, at all reasonable times, on notice, be given the opportunity to examine and to copy all such records.

SEC. 1921. RESEARCH AND EDUCATION.

(a) RESEARCH.—The Secretary shall, in consultation with other Federal agencies and with the States, establish priorities for fish and fish products safety research, such as test methodology for microbiological and chemical contaminants, and the appropriate Federal agencies shall conduct research regarding such priorities.

(b) EDUCATION GRANTS.—The Secretary, acting through the Extension Service, shall provide $2,000,000 each fiscal year out of the funds appropriated to carry out this title to award grants for the establishment of demonstration projects by States, under terms and conditions prescribed by the Secretary, to assist States in conjunction with the Extension Service in providing food safety information and instruction regarding the proper handling, storage and preparation of fish and fish products for human consumption.

(c) SHELLFISH INDICATOR RESEARCH PROGRAM.—

(1) ESTABLISHMENT.—The Secretary of Commerce, in consultation with the Administrator of the Environmental Protection Agency, shall establish and administer, for a 5-year period, a shellfish indicator research program to develop a system of classification of shellfish harvesting areas based on the latest technological advancements in microbiology and epidemiological methods. In establishing such a program, the Secretary of Commerce shall develop a program that shall include the following activities:

(A) ASSESSMENTS.—An assessment of commercial shellfish growing areas in the United States, including the evaluation of the relationships between indicators of fecal contamination and human enteric pathogens.

(B) EVALUATIONS.—An evaluation of the relationships described in subparagraph (A) with respect to potential health hazards associated with human consumption.

(C) COMPARISONS.—A comparison of the current microbiological methods used for evaluation of indicator bacteria and human enteric pathogens in shellfish and shellfish harvesting areas with new technological methods designed for this purpose.

(D) EPIDEMIOLOGICAL STUDIES.—The design of epidemiological studies to relate microbiological data, sanitary survey data, and human shellfish consumption data to actual hazards to health associated with such consumption.

(2) GRANTS.—The Secretary of Commerce shall carry out the research program established under paragraph (1) by providing assistance in the form of grants to eligible applicants.

(3) SOLICITATION.—Not later than 90 days after the date of enactment of this title, the Secretary of Commerce shall publish in the Federal Register a solicitation of research proposals to carry out the research program established under this subsection.

(4) AWARDING OF GRANTS.—Not later than 90 days after the date of the publication of the solicitation under paragraph (3), the Secretary of Commerce shall award a grant or grants to eligible applicants to carry out the research program established under this subsection.

(5) ELIGIBLE APPLICANT.—As used in this subsection, the term eligible applicant means—

(A) any public or private institution of higher education;

(B) any public or private organization with suitable research capabilities; or

(C) any consortium of two or more entities referred to in subparagraphs (A) and (B).

(d) ADVISORY PANEL.—The Secretary shall establish an advisory panel, consistent with the requirements of the Federal Advisory Committee Act, to assist in the development and implementation of the research programs under this section. Such advisory panel shall include one representative each from the Environmental Protection Agency, the Food and Drug Administration, the Department of Commerce, the Fish and Wildlife Service, the Interstate Shellfish Sanitation Conference, appropriate State health authorities and a representative from the commercial fish industry and from a public interest group.

(e) PERIODIC REVIEW.—The Secretary shall review the research programs established under this section not less than once every 2 years and, on the basis of that review, make changes in the administration of the programs that are appropriate to carry out more effectively the activities described.

(f) RESEARCH STUDY CONCERNING INSPECTIONS OF HARVESTING AND FISH TENDER VESSELS.—

(1) CONDUCT OF STUDY.—

(A) IN GENERAL.—Not later than 2 years after the date of enactment of this title, the Secretary, in cooperation with the Secretary of Commerce shall conduct and complete a study of—

(i) the role of fish tender and fish harvesting vessels in safeguarding the wholesomeness of fish products;

(ii) the potential necessity of requesting the Secretary of Commerce, in cooperation with the Coast Guard and the States, to establish procedures for the registration of commercial fishing vessels, fish processing vessels, and fish tender vessels; and

(iii) based on a scientific analysis, the potential necessity of including any particular type or class of such vessels in the inspection program conducted pursuant to this title.

(B) UPDATE.—The Secretary, in cooperation with the Secretary of Commerce, may from time to time update the study conducted under subparagraph (A) and shall on completion of such study or after any such updates, immediately submit to the Committees on Agriculture and Merchant Marine and Fisheries of the House of Representatives and the committees on Agriculture, Nutrition, and Forestry and Commerce, Science, and Transportation of the Senate, the results of such study and the results of any update of such study.

(2) CONCLUSIONS.—If as a result of the study conducted under paragraph (1) or any update of such study the Secretary concludes, in consultation with the Secretary of Commerce, that any type or class of vessels not subject to inspection should be

subject to inspection, the Secretary shall so advise the Committees described in subparagraph (B) of paragraph (1).

(g) OTHER RESEARCH.—The Secretary shall conduct and support research concerning—

(1) the testing of methodology for detecting and measuring biological and chemical contaminants in fish products;

(2) the techniques and procedures utilized for inspecting fish and fish products;

(3) the sanitation practices for the harvesting, processing, transportation, and storage of fish and fish products; and

(4) any other matters that may further the purposes of this title.

(h) REPORTS TO CONGRESS.—The Secretary of Agriculture in cooperation with the Secretary of Commerce shall prepare and submit, to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate, a biennial report concerning the research and education programs authorized and established under this section. Such reports shall be made available to appropriate Federal and State agencies, the fish industry, and the general public. Each such report shall include, with respect to the period for which such report was prepared—

(1) a description of the research assisted under this section and the results of such research;

(2) all changes that were made in the administration of the programs established under this section subsequent to the date of the previous report; and

(3) any recommendations for legislative action to improve the effectiveness of the inspection program for fish products.

SEC. 1922. MISCELLANEOUS.

(a) PROHIBITION ON COPYING OF OFFICIAL MARKS.—No brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, or any form of certificate or simulation thereof, except as authorized by the Secretary.

(b) COMPLIANCE.—No establishment processing fish products for interstate commerce or otherwise subject to this title shall process any fish product except in compliance with this title.

(c) ENTRY OF ARTICLES INTO ESTABLISHMENTS.—The Secretary may limit the entry of fish products and other materials into any establishment, under such conditions as the Secretary may prescribe to assure that permitting the entry of such products into such establishments will be consistent with the purposes of this title.

(d) CONDEMNATION OF SEIZURE.—This title shall not be construed to limit the authority of the Secretary to condemn or seize property that is conferred by provisions of other laws.

(e) ADMINISTRATIVE DETENTION, CONDEMNATION.—

(1) ADMINISTRATIVE DETENTION.—When any fish product is found by any authorized representative of the Secretary on any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to the requirements of this title, and there is reason to believe that any such prod-

uct is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of this title or any other Federal law or the laws of any State or Territory, or the District of Columbia, or that it has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period of not to exceed 20 days, pending notification of any Federal, State, or other governmental authorities having jurisdiction over such product, and shall not be moved by any person, from the place at which it is located when so detained, until released by such representative. All official marks may be required by such representative to be removed from such product before it is released unless it appears to the satisfaction of the Secretary that the product is eligible to retain such marks.

(2) CONDEMNATION.—

(A) LIBEL OF INFORMATION; JURISDICTION.—Any fish product that is being transported in commerce or otherwise subject to the requirements of this title, or that is held for sale in the United States after such transportation, and that—

(i) is or has been processed, sold, transported, or otherwise distributed or offered or received for distribution in violation of this title;

(ii) is capable of use as human food and is adulterated or misbranded; or

(iii) in any other manner is in violation of this title;

shall be liable to be proceeded against and seized and condemned at any time, on a libel of information in any United States district court or other proper court as provided for in this title within the jurisdiction of which the product is found.

(B) DISPOSAL.—If a fish product is condemned it shall, after the entry of the decree of condemnation—

(i) be distributed in accordance with regulations promulgated by the Secretary; or

(ii) be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but such product shall not be sold contrary to the provisions of this title, or the laws of the jurisdiction in which it is sold.

On the execution and delivery of a good and sufficient bond conditioned that the fish product shall not be sold or otherwise disposed of contrary to the this title, or the laws of the jurisdiction in which the disposal is made, the court may direct that such product be delivered to the owner thereof subject to such supervision by authorized representatives of the Secretary as is necessary to insure compliance with the applicable laws.

(C) COURT COSTS AND FEES.—When a decree of condemnation is entered against a fish product and such product is released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against

the person, if any, intervening as claimant of the fish product.

(D) PROCEEDINGS.—The proceedings in libel cases under this subsection shall conform, as nearly as may be, to the proceedings in admiralty, except that either party may demand a trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(3) ADMINISTRATION AND ENFORCEMENT.—For the efficient administration and enforcement of this title, the provisions (including penalties) of sections 46, 48, 49, and 50 of title 15, United States Code (except subsections (c) through (h) of section 46 and the last paragraph of section 49 of such title) and the provision of section 409l of title 47, United States Code, shall be applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this title and to any person with respect to whom such authority is exercised. The Secretary, in person or by such agents as the Secretary may designate, may prosecute any inquiry necessary to carry out the duties of the Secretary under this title, and the powers conferred by sections 49 and 50 of title 15, United States Code, on the district courts of the United States may be exercised for the purposes of this title.

(f) JURISDICTION.—Except as otherwise provided in this title, the United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and the United States courts of the other territories, are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this title and shall have jurisdiction in all other kinds of cases arising under this title. All proceedings for the enforcement or to restrain violations of this title shall be by and in the name of the United States.

(g) SEVERABILITY.—If any provision of this title, or the application of such provision to any person or circumstance is held to be unconstitutional or otherwise invalid, the remainder of this title, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

SEC. 1923. REGULATIONS.

(a) ISSUANCE.—The Secretary shall issue regulations necessary or appropriate to carry out this title in accordance with the informal notice and prior public comment requirements of section 553 of title 5, United States Code.

(b) COPY AND JUSTIFICATION.—Not later than 5 days prior to issuing of any regulation under subsection (a), the Secretary shall provide to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a copy of the regulation and a statement in justification of the regulation.

SEC. 1924. INTERAGENCY COOPERATION.

The Secretary may, by agreement with the head of any Federal agency, utilize on a reimbursable basis or otherwise, the personnel, services, and facilities of any other department or agency of the

United States in the performance of the duties of the Secretary under this title.

SEC. 1925. EXEMPTION FROM FEDERAL FOOD, DRUG, AND COSMETIC ACT.

The inspection, sampling or regulation of fish products, and the handling, processing, storage, or transportation of fish products, shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) to the extent that this title applies to such fish products, or the handling, processing, storage, or transportation of fish products, except that this title shall not diminish any authority conferred by the Federal Food, Drug, and Cosmetic Act prior to the implementation or enforcement of this title under section 5 of the Fish Safety Act of 1990.

SEC. 1926. COST OF INSPECTION, OVERTIME.

The cost of inspections rendered under the requirements of this title, shall be borne by the United States, except that the cost of overtime and holiday work required in establishments at such rates as the Secretary may determine shall be borne by establishments. Sums received by the Secretary in reimbursement for sums paid out by the Secretary for such premium pay work shall be available without fiscal year limitation to carry out this title.

SEC. 1927. AUTHORIZATION OF APPROPRIATIONS.

(a) INSPECTION PROGRAM.—There are authorized to be appropriated to carry out this title, not to exceed $14,000,000 for fiscal year 1991, $40,000,000 for fiscal year 1992, $80,000,000 for fiscal year 1993, and $100,000,000 in each of the fiscal years 1994 and 1995.

(b) RESEARCH PROGRAMS AUTHORIZATION.—Of the amounts appropriated under subsection (a), the Secretary shall use not to exceed $5,000,000 in each of the fiscal years 1991, 1992, and 1993, to carry out the research programs under section 1921 of this title.

SEC. 1928. EFFECTIVE DATE.

This title shall become effective on the date of enactment of this title.

SMITH-LEVER ACT

SEC. 1. In order to aid in diffusing among the people of the United States useful and practical information on subjects relating to agriculture, uses of solar energy with respect to agriculture, home economics, and rural energy, and to encourage the application of the same, there may be continued or inaugurted in connection with the college or colleges in each State, Territory, or possession, now receiving, or which may hereafter receive, the benefits of the Act of Congress approved July second, eighteen hundred and sixty-two, entitled "An Act donating public lands to the several States and Territories which may provide colleges for the benefit of agriculture and the mechanic arts" (Twelfth Statutes at Large, page five hundred and three) and of the Act of Congress approved August thirtieth, eighteen hundred and ninety (Twenty-sixth Statutes at Large, page four hundred and seventeen and chapter eight hundred and forty-one), agricultural extension work which shall be carried on in cooperation with the United States Department of Agriculture: *Provided*, That in any State, Territory, or possession

in which two or more such colleges have been or hereafter may be established, the appropriations hereinafter made to such State, Territory, or possession shall be administered by such college or colleges as the legislature of such State. Territory, or possession may direct. For the purposes of this Act, the term "solar energy" means energy derived from sources (other than fossil fuels) and technologies included in the Federal Non-Nuclear Energy Research and Development Act of 1974, as amended.

SEC. 2. Cooperative agricultural extension work shall consist of the development of practical applications of research knowledge and giving of instruction and practical demonstrations of existing or improved practices or technologies in agriculture, uses of solar energy with respect to agriculture, home economics, *food safety,* and rural energy, and subjects relating thereto to persons not attending or resident in said colleges in the several communities, and imparting information on said subjects through demonstrations, publications, and otherwise and for the necessary printing and distribution of information in connection with the foregoing; and this work shall be carried on in such manner as may be mutually agreed upon by the Secretary of Agriculture and the State agricultural college or colleges or Territory or possession receiving the benefits of this Act.

SEC. 3. (a) There are hereby authorized to be appropriated for the purposes of this Act such sums as Congress may from time to time determine to be necessary.

(b)(1) Out of such sums, each State and the Federal Extension Service shall be entitled to receive annually a sum of money equal to the sums available from Federal cooperative extension funds for the fiscal year 1962, and subject to the same requirements as to furnishing of equivalent sums by the State, except that amounts heretofore made available to the Secretary for allotment on the basis of special needs shall continue available for use on the same basis.

(2) There is authorized to be appropriated for the fiscal year ending June 30, 1971, and for each fiscal year thereafter, for payment to the Virgin Islands, Guam, and the Northern Mariana Islands, $100,000 each, which sums shall be in addition to the sums appropriated for the several States of the United States and Puerto Rico under the provisions of this section. The amount paid by the Federal Government to the Virgin Islands, Guam, and the Northern Mariana Islands pursuant to this paragraph shall not exceed during any fiscal year, except the fiscal years ending June 30, 1971, and June 30, 1972, when such amount may be used to pay the total cost of providing services pursuant to this subchapter, the amount available and budgeted for expenditure by the Virgin Islands, Guam, and the Northern Mariana Islands for the purposes of this subchapter.

(c) Any sums made available by the Congress for further development of cooperative extension work in addition to those referred to in subsection (b) hereof shall be distributed as follows:

(1) Four per centum of the sum so appropriated for each fiscal year shall be allotted to the Federal Extension Service for administrative, technical, and other services, and for co-

ordinating the extension work of the Department and the several States, Territories and possessions.

(2) Of the remainder so appropriated for each fiscal year 20 per per centum shall be paid to the several States in equal proportions, 40 per centum shall be paid to the several States in the proportion that the rural population of each bears to the total rural population of the several States as determined by the census, and the balance shall be paid to the several States in the proportion that the farm population of each bears to the total farm population of the several States as determined by the census: *Provided,* That payments out of the additional appropriations for further development of extension work authorized herein may be made subject to the making available of such funds by the States from non-Federal funds for the maintenance of cooperative agricultural extension work provided for in this Act, as may be provided by the Congress at the time such additional appropriations are made: *Provided further,* That any appropriation made hereunder shall be allotted in the first and succeeding years on the basis of the decennial census current at the time such appropriation is first made, and as to any increase, on the basis of decennial census current at the time such increase is first appropriated.

(d) The Federal Extension Service shall receive such amounts as Congress shall determine for administration, technical, and other services and for coordinating the extension work of the Department and the several States, Territories, and possessions.

(e) Insofar as the provisions of subsections (b) and (c) of this section, which require or permit Congress to require matching of Federal funds, apply to the Virgin Islands of the United States and Guam, such provisions shall be deemed to have been satisfied, for the fiscal years ending September 30, 1978, and September 30, 1979, only if the amounts budgeted and available for expenditure by the Virgin Islands of the United States and Guam in such years equal the amounts budgeted and available for expenditure by the Virgin Islands of the United States and Guam in the fiscal year ending September 30, 1977.

(f)(1) The Secretary of Agriculture may conduct educational, instructional, demonstration, and publication distribution programs through the Federal Extension Service and enter into cooperative agreements with private nonprofit and profit organizations and individuals to share the cost of such programs through contributions from private sources as provided in this subsection.

(2) The Secretary may receive contributions under this subsection from private sources for the purposes described in paragraph (1) and provide matching funds in an amount not greater than 50 percent of such contributions.

(g) There are authorized to be appropriated for each of the fiscal years 1991 through 1995, $750,000 for additional programs to be administered by the Secretary of Agriculture through the Extension Service to disseminate food safety information, publications, and instruction to consumers, restaurant food handlers, schools and other persons concerning the proper handling, storage and preparation of fish products.

* * * * * * *

APPENDIX

Summary

Aquaculturally produced animals are safe and healthy products. Culture conditions for commerical catfish and trout production help ensure fish are grown in a controlled, clean environment and are fed a healthy safe diet. The potential for drug or other chemical residues in pond or raceway produced catfish or trout from disease treatment is low if producers follow established federal guidelines.

Introduction

Aquaculture production of shellfish or fish in oceans estuaries, lakes or rivers creates the potential for the same human safety concerns as harvested wild fish or shellfish although known aquacultural practices (depuration) could be utilized to help ensure a safe product. Most health concerns that might arise from aquaculture products will arise because of poor quality control by disreputable producers, processors or marketers.

Current voluntary inspection programs in the catfish and trout industries utilitize the United States Department of Commerce (USDC) guidelines and inspectors. The Hazard Analysis Critical Control Point (HACCP) model appears suitable for aquaculture products and is already in place for some of them.

Aquaculture is underwater agriculture. It is the rearing and often the propagation of aquatic organisms under controlled or semi-controlled conditions. Aquaculure includes the production of animals for human consumption and sport as well as their production for bait, for ornamental and pet purposes, and for stocking or restocking programs to augment natural fisheries. The production of aquatic organisms may occur in freshwater, estuarine or saltwater environment at warm, cool or cold temperature; and may involve a species' entire life cycle, or only a brief part of the life cyle.

Production may be intensive with high management and financial inputs producing high yields per water volume or extensive with lower yields and low managment or financial input. Aquaculturists may be professionals or amateurs who may raise aquatic animals for their livelihood, as a hobby or to provide supplemental income or food.

Production of some aquatic animals is based on well established principles while for others it is still experimental with production practices still evolving. Some animals are reared in static ponds, some in raceways with flowing water and some in cages or pens in ponds, lakes, reservoirs, rivers, estuaries or oceans. Some animals,

such as the mollusks, may spend the bulk of their lives on estuarine or sea-floor bottoms or suspended in the water column.

In short, aquaculture is very diverse, is expected to expand greatly and its products will constitute a larger portion of human protein consumption in the next decade.

This paper presents information about aquaculture and food safety. As such its focus will be on those aquatic animals currently reared for human consumption. Specifically, we will describe the variety of fin and shellfish raised and harvested by aquaculturists, discuss various attributes of the aquaculture industry and related health problems of concern to the consuming public, discuss current regulations of the industry regarding food safety, discuss possible effects of a federally mandated food safety inspection program on aquaculture and conclude with an analysis of the HACCP model on which a mandatory seafood (aquaculture) inspection program may be based.

AQUACULTURE

Commercial finfish acquaculture in the U.S. focuses on the production of channel catfish (*Ictalurus punctatus*) and rainbow trout (*Oncorhynchus mykiss*) although other finfish are raised as well (Table 1, omitted in this reprint). Salmonids, primarily the Pacific salmon (varius *Oncorhynchus spp.*) and Atlantic salmon (*Salmo salar*) were until recently cultivated in hatcheries for stocking programs. These fish are now reared commercially in net pens in estuaries or oceans and harvested for human use.

Catfish

Farm raised channel catfish is the largest aquaculture industry in the U.S. ith annual production well over 340 million lbs. of live fish. Of these, Mississippi produces approximately 80 (91,000 acres), followed by Arkansas (18,600 acres), Alabama (15,000 acres), and Louisiana (12,000 acres. The majority of catfish production occurs in static water ponds averaging 15 surface acres which are 4 feet deep. Approximately 80% of catfish production is marketed through commercial processors. Water is obtained from shallow wells or watersheds.

Catfish broodstock are held in small ponds throughout the year. These generally spawn in May-June and produce gelatinous egg masses which are removed from the nest and placed in a hatchery for development. Eggs hatch in 5–7 days if held in warm water (78–82° F)., Once eggs hatch and the yolk sac is absorded, fry are fed a commercially prepared high protein diet (48 protein). After several days, the fry are stocked into ponds (up to 500,000 fry per acre), fed and progressively thinned out as the fish grow, Once fry reach a suitable size, they are stocked into food fish production ponds with older, larger fish. They will be fed once or twce daily and after 15–18 months fish will be harvested at 0.75–1.5 lbs each.

Ideally catfish ponds are filled with high quality well water free of contaminants. This helps ensure a quality product and supplies the fish with water free of pathogens. The soil generally has a high clay content (at least 20% clay) to prevent water leakage. A flat topography makes pond construction easier and more economical.

Land devoted to aquaculture was often previously used for grain or cotton product. To prevent pesticide problems, soils are checked for pesticide residues prior to pond construction. Soils exceeding an arbitrarily derived pesticide limit (toxaphene, 0.5 ppm) are removed exposing cleaner soils. Feed is generally composed of grains as follows:

Soybean meal	50.5
Corn grain	32.0
Fish meal	8.0
Wheat middlings	60.0
Dicalcium phosphate	1.5
Fat (sprayed on finished feed)	1.5
Vitamin mix	.05
Mineral mix	.05
Ascorbic acid	.04

Before harvesting and processing, catfish are evaluated for quality by experienced tasters (organoleptic analysis). Sample fish are removed from the pond and tested approximately two week before harvest, the day before harvest and the day of harvest. Fish are harvested by seining, hauled alive to a processing plant and unloaded into a holding vat. They are then placed into a basket, stunned by electrical current and conveyed into a plant where they are deheaded, eviscerated, skinned, washed and chilled.

After chilling approximately 50% of the fish are marketed as ice pack whole fish, fillets, strips or steaks. The remainng 50% are marketed as frozen whole fish fillets, strips or steaks. Fish may also be further processed into breaded products, both portion controlled and natural fillets, and flavor marinated products. Once fish are delivered live to the processing vat the processing time is approximately 30 minutes. Offal, the byproduct of catfish processing is sent to a rendering plant for further processing into fish meal and fish oil, ingredients used in animal fed, or it is ground, cooled and then sold to pet food companies as an ingredient in canned pet food.

Commercially processed fish are marketed throughout the U.S to retail grocery outlets and the food service sector. Each accounts for approximately half of total catfish sales. The per capita consumption of all seafood is 15.1 lbs. in the U.S. and the per capita consumption of processed catfish is 0.75 pounds.

Variations in these production processing and marketing practices occur. Some catfish are raised in raceways, net pens or enclosed tanks inside buildings. These tanks have recirculated water. Feed composition may vary. Farmers may process the fish themselves and sell directly to stores and consumers, although most fish farmers sell directly to processing plants.

Rainbow trout

Rainbow trout are raised throughout the U.S. wherever cold clean water is available (optimal temperature is 50–60° F) but the bulk of production occurs in Idaho. One large, totally integrated production system may produce and process 18 million pounds annually. Total U.S. trout production is estimated at 50–60 million pounds annually.

Most trout production occurs in cement or fiberglass raceways and ponds receiving cold stream water. The trout water must be

free of contaminants or fish will not survive. Increased emphasis is being placed on water reuse, Trout generally spawn once per year at a temperature of 50–55° F. By careful genetic selection and manipulation of day length with lights, some producers are able to stagger the normal spawning cycle to provide a continuous supply of eggs throughout the year.

An artifical spawning method is frequently used in which the sex products of the fish are manually stripped from the fish, mixed in a container, and the placed in an incubator receiving cold water (50–60° F). Broodfish are then returned for later use. Eggs are incubated for 19–48, days depending on temperature, until hatching. Fry will feed off a yolk sac for approximately 25 days after which they are fed as commercially prepared high protein (50%) feed. As the fish mature they are fed progressively less protein (30–40%). A typical trout diet consists of fish meal and fish oils, meat and poultry products, corn and soybean meal, and vitamins and minerals. The proportions of each may be varied depending on need.

Rainbow trout are most often fed by an automatic feeder fitted with a timing device that provides fish with small quantities of feed at frequent intervals. Fish are generally harvested after 1 year when each fish weighs 1 to 14 ounces. Processing consists of machine evisceration, visual quality inspection and then into chill tanks. Fish are packaged as dressed trout or further processed as boned, boned and deheaded or filleted. Variations in this aquaculture production scheme also occur. Some trout are raised in earthen ponds and some in cages located in ponds, lakes, cold reservoirs, or coastal waters.

Salmon

As previously mentioned, some sea-farming of salmonids (salmon) and related fish occurs. In these production schemes, up-stream migrating salmon are captured, sex removed for spawning, eggs incubated and hatched and fry fed an artificial diet until a suitable size for stocking (smolfts). Smolts are stocked into sea pens for rearing. These fish are fed a commercially prepared diet and harvested at 0.75–1.5 pounds.

Processing generally occurs immediately after harvest. The net pens themselves are bound together by narrow wood and metal walkways floating over waters often 100–200 feet deep. In emergencies these pens can be moved to different locations. Water flows through the pens and fish are fed by automatic feeders or by hand.

Shrimp

Shrimp aquaculture (Table 2) has grown rapidly in foreign countries, but slowly in the U.S. Shrimp farmers now produce 26% (565,000 metric tons of live shrimp) of the shrimp placed on world markets. China for example produces approximately 30% of all farm raised shrimp, the bulk of which is imported into the U.S. Of all shrimp consumed in the U.S. (800 million lbs.), over 22% comes from overseas aquacultural production. Most U.S. marine shrimp aquaculture occurs in Texas, Florida, South Carolina and Hawaii.

Most shrimp farming is conducted in seawater impoundments near tidally active areas. This allows water in the ponds to be periodically replenished. Shrimp farming involves the production of

seed stock in a hatchery, transfer of postlarvae to a growout pond with supplemental feeding and finally harvest. Once a shrimp pond is stocked, it takes from three to six months to produce a crop of market sized shrimp. After harvest shrimp are held on ice for sale as fresh shrimp or frozen.

Seawater for the hatchery or pond is pumped directly from the water column or from a sub-sand well point on a nearby beach. Estuarine water is not used in the hatchery because of frequent variations in salinity. Hatcheries may rely on flow-through water or closed water recycling systems. Larval shrimp require a constant salinity of 25–35 ppt and are fed algae, small 300 plankton (*Artemia nauplii*) and finally a commercially prepared ground pellet as they increase in size.

Once the shrimp are moved to a pond, estuarine water may be used. Ponds vary in size from 25–50 acres for semi-intensive production to 0.25–2.5 acres for intensive, high management production. Generally, successful yields are 1,800–3,000 lbs whole shrimp per acre per year.

Crayfish

Crayfish are raised commercially on approximately 150,000 acres in the U.S., and Louisiana dominates the industry with 135,000 acres in production. Other crayfish producing states include Texas, Arkansas, Mississippi, Florida, South Carolina, North Carolina, and Maryland. Industry value approaches $100 million annually. Crayfish are typically cultured in earthen ponds in a semi-intensive system where they forage on flooded vegetation and the microbial community associated with vegetative decay. Harvest is by daily trapping with baited traps, and the harvest season extends from fall through spring.

In Louisiana a substantial acreage is farmland where crayfish are either double cropped or rotated with agronomic crops. A significant "wild crop" is harvested from natural waters in Louisiana, and in some years, this wild crop equals or exceeds that produced in aquaculture ponds.

In a typical production pond, adult broodstock are stocked in the spring at the rate of 50–75 lb/acre and allowed to burrow underground to spend the dry summer months. While the pond is dry a forage crop, usually rice or sorghum, is planted and cultivated. The grain crop may be harvested, or the entire plant may be left to provide fodder for subsequent crayfish production. The pond is flooded in the early fall and broodstock emerge from the burrows with their broods of young produced during the summer. These, in effect, stock the pond and grow to harvestable size in 9–12 weeks. Daily trapping is used to harvest adult crayfish, and usually the season extends to 125–150 trapping days. The ponds are drained in late spring, at which time residual adult crayfish burrow underground to repeat the production cycle. Crayfish are marketed live or as frozen tails after processing.

Mollusks

Mollusks (oysters, mussels and similar shellfish) are generally raised similary to shrimp. Seed stock is obtained and reared in well controlled hatcheries using purified seawater or artificial seawater.

After reaching a critical size as spat, they are placed on sea beds or on ropes or other structures suspended vertically in the water column. They are harvested after six months to several years of growth depending on species. The bulk of mollusk farming in the U.S. occurs along the Pacific and Atlantic coasts.

While some mollusk production on the Pacific Coast may be pure aquaculture in that seed stock is produced in hatcheries and cared for during their entire life cycle, other areas of the United States practice molluscan aquaculture in a less controlled setting. In these ventures seed stock is harvested from public reefs and removed for culture to privately owned leases. These private leases play an increasingly important role in providing oysters to the public.

It should be noted that environmental factors are having a major negative impact on the U.S. oyster industry. One solution to this is the establishment of a depuration system which would allow utilization of oysters from waters not certified for shellfish harvest. In this system shellfish are moved to clean, tank water and allowed to purge themselves (depurate) of contaminants. Another system is to move the shellfish to clean ocean (relay) to depurate. The establishment of such systems will not only expand the scope of private leases, but open public reefs for oyster harvest as well.

HEALTH CONCERNS

Due to the unique controlled environment in which most aquaculturally reared animals are produced, there are few uniquely aquaculture associated human health concerns. Careful water qualify management, short production times and rapid processing means no or limited exposure times to chemical or microbial contaminants.

Some microbial contaminants, natural toxins and decomposition products could be associated with aquaculture animals (particularly those exposed to natural bodies of water) which could be of concern to human health but these are common to all seafoods. One unique safety concern to aquaculturally produced animals relates to use of feed additives, drugs and other therapeutants. Each issue will be addressed below.

Toxic chemicals

Toxic chemicals in the aquatic environment could contaminate fish and shellfish. These chemicals may be naturally produced, accidentally introduced or intentionally incorporated into feeds.

Natural toxins

Certain microbes may produce toxins which are of human safety concern. While never reported and unlikely to occur in farm raised channel catfish or trout, they could occur in aquaculturally raised marine animals. These toxins (ciguatera toxins, saxitoxins, brevetoxins, domoic acid, and dinophsistoxins) can be produced by certain algae or bacteria (histamine). Histamine poisoning is associated with bacterially mediated spoilage.

Various dinoflagellates and certain other marine planktonic algae may produce a toxin which can bioaccumulate in fish and shellfish. Paralytic shellfish poisoning (PSP) due to *Gonyaulax ca-*

tenella and *G. tamarensis*, neurotoxic shellfish poisoning (NSP) due to *Ptychodiscus brevis* (the red tide organism) and diarrhetic shellfish poisoning (DSP) caused by toxins produced by *Dinophysis fortii* and *D. acumanita* may occur following the consumption of several different kinds of raw or cooked filter feeding shellfish. Some of these same toxins may also kill fish.

Accidental toxins

These chemicals include pesticides, heavy metals, petroleum hydrocarbons, nitrosamines, and radionuclides. Those aquatic animals reared in natural water bodies such as the ocean, estuaries or rivers are more likely subject to these contaminants because of waste discharge, leachate from toxic waste dump sites, accidents and illegal dumping than are channel catfish or trout. This may be of particular concern for some fish because they are known to bioaccumulate up to 100-times ambient levels.

Bioaccumulation usually occurs via cycling up the food chain. As long as feed ingredients themselves are not contaminated, pesticide problems should be minimal. Watershed runoff or aerially applied pesticides falling into aquaculture facilities could cause some contamination. Approximately 90% of all catfish farms receive water from wells and not runoff. Recent surveys by catfish processors of farm raised catfish indicate these fish do not exceed federal action levels for pesticide residues (Table 3). A study conducted by the United States Department of Agriculture (USDA) using sensitive techniques indicted no pesticides could be detected in catfish pond water.

TABLE 3. ACTION LEVELS OF POISONOUS OR DELETERIOUS CHEMICALS IN EDIBLE SEAFOOD PORTIONS

Chemical	Seafood group	Action level (pm)
Aldrin and dieldrin	Fish	0.3
Benzene hexachloride	Frog legs	.3
Chlordane	Fish	.3
DDT, DDE, TDE	Fish	5.0
Endrin	Fish	.3
Heptachlor and Heptachlor epoxide	Fish and shellfish	.3
Kepone (chlordecone)	Crabs	4
	Eels	.1
	Finfish	.3
	Oysters	.3
Mercury (methy mercury)	Fish, shellfish and crustaceans; and other aquatic animals	1.0
Mirex	Fish and shellfish	.1
PCBs	Fish	5.0
Toxaphene	Fish	5.0

Since aquaculture animals are frequently fed a commercially prepared diet, contamination of various feed ingredients may occur. Grains used in various fish feeds could be contaminated by mycotoxins, various pesticides or bacteria. What impact these might have on fish is unknown nor is it known if these could be of human safety concern. Research in this area is needed.

Chemical intentionally incorporated in feed

Aquaculturally produced fish to have the potential to cause human safety concerns because of feed additives or drugs. Currently, only 6 therapeutants, 4 disinfectants, 6 water treatment compounds and dyes, 3 anesthetics, 12 herbicides and 2 fish toxicants are registered for use in aquaculture (Table 4). Most of the products are for use only with finfish. All medicated feed manufacturers are required to be in compliance with good manufacturing practices otherwise they are in violation of federal regulations.

TABLE 4.—COMPOUNDS REGISTERED OR APPROVED FOR USE IN AQUACULTURALLY PRODUCED ANIMALS DESTINED FOR HUMAN CONSUMPTION

Withdrawal product	Use	Time
Oxytetracycline (Terramycine for fish)	Antibacterial for fish and lobster	21 days.
Romet-30 or Romet-B	Antibacterial for catfish or salmon	3 days (catfish), 42 days (salmon).
Formalin F	Parasiticide and fungicide for various fish	None.
Copper (elemental)	Antibacterial for penaed shrimp	None.
Sodium chloride	Osmoregulatory enhancer	None.
Vinegar	Parasiticide for fish	None.
Didecyl dimethyl for equipment ammonium chloride.	Disinfectant	
Povidone-iodine	Disinfectant of fish eggs	None.
Quaternary ammonia	Disinfection of water, gear and tanks	None.
Fluorescein sodium	Dye	None.
Lime	Pond sterilant	7 day (oral).
Oxytetracycline	Dye to mark fish	15 day (injectable).
Potassium permanganate	Oxidizer	None.
Rhodamine B and WT	Dye for water flow analysis	None.
Carbonic acid	Anesthetic for fish	None.
MS-222	Anesthetic for fish	21 days.
Sodium bicarbonate	Anesthetic for fish	None.
Acid blue and acid yellow	Algacide	None.
Aluminum sulfite	Algacide	None.
Copper, elemental	Algacide	None.
Copper sulfate	Algacide	None.
2,4-D	Herbicide	None.
Diquat	Algacide	None.
Endothal	Herbicide	3 days.
Fluridone	Herbicide	None.
Glyphosate	Herbicide	None.
Potassium ricinoleate	Algacide	4 weeks.
Simazine	Algacide	None.
Xylene	Herbicide	None.
Antimycin	Piscicide	None.
Rotenone	Piscicide	None.

Diseases are an ever-present concern for aquaculturists because they are often rearing animals under confined, intensive conditions which foster the occurrence and spread of various diseases. This risk of disease and loss may be particularly important in fish and shellfish hatcheries, where large numbers of fingerlings or other seed stock are produced under intensive culture conditions. It is in these areas, with fish in the vulnerable egg or larval stages and many months away from harvest, that prohibition on the use of certain therapeutants may be overlooked.

Effective therapeutants for use in hatcheries are needed. The lack of therapeutants hampers effective disease control and could

foster illegitimate use of compounds or failure to observe estab lished withdrawal times. This could result in drug residues of potential human safety concern. There is also the potential for transfer of antibiotic resistant bacteria to humans. Certain illegal color additives may also be used in feeds to promote an orange or red color in salmon flesh. There is concern about residues in imported aquaculture products. There is currently very little uniform inspection of imported products and it is feared that many chemicals not used in the U.S. are being used in overseas aquaculture.

Microbial factors

Bacteria which cause human disease

Fish and shellfish may harbor various bacteria including strains pathogenic for fish or humans. Fish and shellfish are largely a product of their environment and as such bacteria present in the water may be found on the skin, gills or in the gastrointestinal tract of the fish. If these bacteria include strains, pathogenic for humans, health concerns may arise. This may be of particular concern if the aquaculturally produced animal is consumed raw. Human health problems, while rare, can occur and are frequently associated with consumption of raw, of undercooked seafood or cooked seafood subsequently contaminated. Cooking all seafoods destroys these bacteria.

Certain species such as *Vibrio parahemolyticus, V. vulnificus, V. cholerae,* and *Shigella spp.* are known to cause human illness and may occur in aquatic habitats associated with shellfish. The presence of *Listeria monocytogenes* on aquaculturally produced animals has not been demonstrated but is of potential concern because of its apparent ubiquity. Contamination with *Yersinia enterocolitica,* may also be of concern. *Clostridium botulinum* toxicity (botulism) has been associated with consumption of contaminated canned or smoked salmon. Although these salmon were not aquaculturally produced, there is nothing unique about aquaculture that would protect them from contamination. The problem arose because of improper processing.

A trend towards extending the shelf-life of refrigerated items including fish products poses a potential safety hazard. This increased shelf-life is due to advances in packaging development such as modified atmosphere storage. Bacterioligic surveys of farm raised channel catfish gastrointestinal tracts indicate a potential for contamination from *Escherichia coli* and various *Clostridium spp.* The source of these bacteria has not been ascertained.

Bacteria which cause fish disease

Fish and shellfish themselves are subject to bacterially mediated diseases. Bacteria associated with these diseases are mostly unique pathogens of fish and are of no concern to humans. An exception is *Aeromonas hydrophila,* the cause of motile *Aeromonas septicemia* in fish, and *Plesiomonas shiggeloides* also causing disease in fish. Both of these bacteria have been associated with diseases in debilitated humans.

Viruses

Human enteric viruses may occur in aquatic environments and these viruses may contaminate aquaculturally produced shellfish. While the viruses probably do not replicate in the shellfish, large numbers may occur. For example, the hepatitis viruses have been demonstrated to be the cause of both food and waterborne disease outbreaks. Cooking of the seafood should eliminate the viruses.

A common practice to eliminate possible shellfish contamination problems is to depurate or relay. These methods allow for the self-purification of the shellfish through normal feeding, digestion and excretion in unpolluted environments, however, economic considerations often limit these activities. None of the viruses causing fish or shellfish disease are believed to be transmissible to man.

Parasites

Certain metazoan parasites found in fish are of concern for human health. These are very unlikely to occur in farm raised catfish or trout because of the general husbandry practices involved in their successful propagation. Also, they are easily killed by freezing or cooking. Various anisakid nematods in marine fish may be a cause for human safety concerns. These particular marine nematodes use fish as second intermediate hosts, the final host being various marine mammals. Human disease results from consumption of contaminated raw or undercooked fish. Salmon may acquire infection by consumption of the first intermediate host (krill, squid or octopus).

Infection of farm raised salmon, while possible, is unlikely because these fish are fed a commercial diet and are unlikely to consume an infected squid or octopus. Fish may serve as intermediate hosts for another nematode, *Eustrongylides spp.* for which the blue heron is the final host. Farm raised catfish have been reported to be infected with the larvae of this parasite. *Eustrongylides* may cause human peritonitis. The parasite gains access to a human only by the consumption of contaminated raw fish. Fish are also second intermediate hosts for various tapeworms including *Diphllobothrium latum.*

These worms are most frequently encountered in pike, perch, walleye and anadromous fish such as salmon and can only be hazardous to humans if contaminated fish are consumed raw or undercooked. Various other metazoans occur in fish but they are not infective to humans. These metazoans, most notably the digenetic trematode yellow grub (*Clinostomum complanatum*) are of aesthetic concern rather than human safety concerns.

[The analysis of the current inspection system and HACCP is omited in this reprint.]

APPENDIX II

FACTORS AFFECTING MICROBIOLOGICAL QUALITY OF SEAFOODS

DONN R. WARD AND NINA J. BAJ

□ THE FACT that seafoods are "different" from other muscle protein foods appears to be well established. However, just what those factors are that create the differences and how they affect the microbiological character of seafood products may not be fully appreciated. Some factors have very obvious microbiological implications, while others are more subtle. Furthermore, some factors are inherent in the basic composition of seafoods, while others result from handling practices and processes. This article will review the effects of these factors on the microbiological quality of seafoods.

Species and Environment

There are more than 3,000 different commercial species of seafoods throughout the world, and more than 250 in the United States (Otwell, 1986; Martin et al., 1978). Intuitively, it would seem that this great diversity would also give rise to diversity among the bacteriological populations normally associated with the various fish species. While species differences may be important, evidence seems to indicate that the flora of fish is more directly related to environmental factors (Shewan, 1953; Liston, 1955). Shewan (1977) indicated that bacteria are a function of the environment—warm-water fish seem to have a more mesophilic, Gram-positive microflora (micrococci, bacilli, coryneforms), while cold-water fish carry a predominantly Gram-negative population (*Moraxella, Acinetobacter, Pseudomonas, Flavobacterium,* and *Vibrio*).

Several studies have demonstrated that properly handled fish harvested from tropical waters have a substantially longer shelf life than fish harvested from cold waters (Disney, 1976; Sumner et al., 1984; Poulter et al., 1981). On the other hand, a review by Lima dos Santos (1981) on the storage of tropical fish in ice suggests that the broad generalization of longer shelf life for tropical fish needs to be reconsidered. Lima dos Santos' contention is that the case has not been proved, that there are too many variables for direct comparisons, and that there are instances of cold water fish such as halibut and grenadiers having shelf life, on ice, for up to 3 weeks. These differences—tropical water vs cold water, Gram-positive vs Gram-negative native microflora—notwithstanding, spoilage patterns during iced storage are usually quite similar, and are caused by *Pseudomonas* spp. and *Alteromonas putrefaciens* (Barile et al., 1985b.)

Methods of Catch and Onboard Handling

The method by which fish are harvested is often mentioned as influencing the number and types of bacteria on the raw material (Nickelson and Vanderzant, 1976); however, quantitive data are difficult to find. Shewan (1949) demonstrated that trawled fish usually carry bacterial loads 10-100 times greater than line-caught fish. This increase is attributed to dragging along the ocean bottom, which stirs up the mud and contaminates the fish, and to compaction of the fish, causing gut contents to be expressed.

The growing demand for seafood has resulted in an increasing interest in producing quality products. Most of the factors affecting microbiological quality previously mentioned are difficult, if not impossible, to control. Onboard handling, however, is one of the first points where substantial progress is possible.

In 1973, the Food and Agricultural Organization published its *Code of Practice for Fresh Fish* (FAO, 1973), the primary focus being the handling of fish at sea. Section 3.1.1 states: "Fish are extremely perishable food, and should be handled at all times with great care and in such a way as to inhibit the growth of microorganisms. Fish quality deteriorates rapidly and potential keeping time is shortened if they are not handled and stored properly. Much of the fish landed for human consumption is subjected to fairly rough handling treatment. Fish should not be exposed to direct sunlight or to the drying effect of wind, but should be carefully cleaned and cooled down to the temperature of melting ice, 0°C, as quickly as possible. Any careless treatment or delay in reducing the temperature of fish will have a marked effect on their potential keeping time."

Note that one of the suggestions in the quote is that the fish should be carefully "cleaned." The word "cleaned" is not defined, but several states require that certain ground fish be bled, gutted, and gilled on board the fishing vessel. Shewan (1961) points out that the main advantage to gutting is to prevent autolytic spoilage, rather than bacterial decomposition. Indeed, FAO (1973) states that "bad gutting might be worse than no gutting" inasmuch as it can facilitate entry of bacteria into the flesh. Stansby and Lemon (1941) reported that gutting of fresh mackerel could increase rather than diminish bacterial numbers. In a more recent study on board a New England trawler, Samuels et al. (1984) found that gutted cod and haddock actually had lower psychrotrophic counts than did cod immediately after catch, although the differences were not significant. Furthermore, they found that the practice of washing the gutted fish in circulating seawater prior to ice storage had no effect on bacterial numbers, although this practice did remove mud and other visible extraneous matter.

Work by Ravesi et al. (1985) on spiny dogfish demonstrated that microbial numbers on fillets were a function of the level of handling and processing prior to removal of the fillet. In other words, dogfish stored whole had lower counts than gutted fish, which in turn had lower counts than those headed and gutted. Interestingly, however, the researchers recommended gutting if the fishing trip is longer than 2 days, since it results in increased shelf life of the fillets, increases in bacterial counts notwithstanding. On the other hand, if the trips are short (less than 2 days) the fishermen's time would be best spent on adequately icing, and thus rapidly chilling, the whole dogfish. The researchers reported that heading and gutting was not helpful, since removing the head creates another cut surface for potential bacterial contamination and does not benefit shelf life.

Mayer et al. (1986) reported that onboard processing (bleeding, gutting, and gilling) did not extend the shelf life of bluefish, inasmuch as fillets from these fish were very similar in sensory scores to the fillets cut from fish boxed and stored whole. However, the authors pointed out that since the whole bluefish were only on ice 1-2 days before processing, there may not have been a sufficient time lapse to see any quality benefit from onboard processing. This agrees with the suggestions of Ravesi et al. (1985).

The FAO (1973) report recommended that fish should be

Author Ward is Associate Professor, Food Science and Technology Dept., North Carolina State University, Raleigh, NC 27695. Author Baj is Laboratory Technician, Food Quality and Safety Laboratory, Texas A&M University System, 442 Kleberg Center, College Station, TX 77843. Send reprint requests to author Ward.

cooled down to the temperature of melting ice, 0°C, as quickly as possible. The rationale for this should be quite apparent. Barile et al. (1985a) found that the shelf life of Faughn's mackerel, on ice, was reduced by one day for each hour delay in icing or exposure to ambient temperatures of 28–30°C. Moreover, at the point of rejection by a trained taste panel, the fish samples had the following aerobic plate counts at 20°C: fish iced immediately, 10^9 organisms/g; fish iced after a 3-hr delay, 10^7; fish iced after a 6-hr delay, 10^8; and fish iced after 9- and 12-hr delays, 10^8. There was also a distinct change in the spoilage microflora. The principal spoilage organisms after 0–6 hr of delay in icing were *Pseudomonas* spp. and *Alteromonas putrefaciens*, while prolonged delay (9–12 hr) resulted in a final spoilage flora of *Bacillus* spp., *Aeromonas hydrophila*, and *Pseudomonas* spp.

Interestingly, work on trench sardines (Chinivasagam and Vidanapathirana, 1986) indicated little difference between the quality of fish iced immediately after landing and those iced after a 5-hr delay. Other studies (Jayaweera, 1980; DeSilva, 1978) have also reported no detrimental effects from delayed icing, for specific fish, for up to 12 hr. Chinivasagam and Vidanapathirana offered two possibilities as to why delayed icing is apparently not detrimental. One is the low incidence of *Pseudomonas* organisms on tropical fish, and the second is the observation of Poulter et al. (1981) that when warm-water fish are kept at high temperatures, the onset of rigor is slow and of a longer duration, thus delaying bacterial growth. Nonetheless, the work in which Barile et al. (1985a) found that shelf life was reduced by one day for every hour delay in icing was done on a tropical species.

Most large, commercial fishing vessels in the mid-Atlantic and New England regions store their catch on ice in the ship's hold. An exception to this would be smaller vessels which leave the docks early in the morning and return later in the day. These vessels, commonly referred to as day-boats, store fish in the holds but often without ice. Samuels et al. (1984) reported significant increases in the psychrotrophic counts on the surface of non-iced bluefish, stored in the hold of these vessels, from the time of catch to the arrival at the dock. However, there were no significant increases on fish caught at the same time but held in iced coolers.

While the use of ice is beneficial in the preservation of fish quality, it is not without its disadvantages. Holston and Slavin (1965) suggested that some of the undesirable attributes of ice are: a tendency to injure and bruise the flesh, and a leeching of flavor components and nutritionally desirable minerals, as well as water-soluble proteins. Also, icing of fish can be very labor intensive and expensive, in view of the large catches that are typical of some fisheries (Reppond et al., 1985; Lee and Kolbe, 1982). Consequently, systems using some form of mechanically refrigerated seawater (RSW) have begun to replace ice in certain fisheries, especially in the Pacific Northwest (Lee and Kolbe, 1982).

Concerns have been expressed regarding the effects of these systems not only on the microbiological quality of products, but also on physical, chemical, and sensory changes. RSW and carbon dioxide-modified refrigerated seawater (MRSW) have been shown to delay spoilage in shrimp and fish, compared to storage on ice (Bullard and Collins, 1978; Reppond et al., 1979; Reppond and Collins, 1983). Roach et al. (1967) stressed the importance of proper sanitation, especially on RSW installations: "While with iced fish only part of a load may spoil, with fish held in tanks of RSW even under proper conditions there is a danger that all, or nearly all, the fish will be rejected if spoilage occurs." The implications of this statement are underscored in work performed by Lee and Kolbe (1982). In their study, aerobic plate counts (at 25°C) of RSW from a commercial vessel were found to be 7.7×10^4 organisms/mL on day 1, rising to 1.5×10^9/mL on day 8. The authors reported that the recirculating seawater seemed to be quickly contaminated by inadequately cleaned surfaces of the fish hold and by debris remaining in the pipes and on wooden bin boards. The authors' contention seemed to be further supported by the finding that ceiling scrapings of the fish hold yielded a microbial count of 4.5×10^9 organisms/g, even after the hold had been cleaned and sanitized.

Bronstein et al. (1985) examined the storage of dressed salmon in refrigerated freshwater, diluted seawater, seawater, and ice. Although differences between storage media were not consistently statistically significant, bacterial growth in fish held on ice appeared to be more rapid than on fish held in chilled-water systems. The authors suggest that the differences may be due to the more aerobic conditions present during iced storage, which allow the normal aerobic spoilage flora to grow more rapidly.

Several studies have reported the MRSW system, which has CO_2 injected to control bacterial growth by reducing the pH of the brine (Neilson and Barnett, 1973), to be superior to both ice and RSW in slowing product deterioration (Barnett et al., 1971; Bullard and Collins, 1978; Lemon and Regier, 1977; Longard and Regier, 1974).

Fishing Vessel Sanitation

Within the food industry, sanitation of food-contact surfaces and food handling equipment is generally given high priority. On board fishing vessels, however, sanitation as practiced by most food industries is not practical. Moreover, the effect of enhanced vessel sanitation on product quality and shelf life appears to be minimal. Samuels et al. (1984) reported the $\log_{10}$ psychrotrophic counts/in^2 of fish-contact surfaces to be: hand gaffs, 8.2 organisms; decks, 7.3; fish hold, 6.5; and shovels and pushes, 7.7. The researchers went on to report that while the sanitary environment on board commercial fishing vessels could be improved, it was not shown to be detrimental to a well-iced catch. This suggestion is in agreement with the work performed by Huss et al. (1974).

Processing

Given the large diversity of commercially exploited species and the products which can be derived from them, the term "processing" can encompass operations which range from the very simple to the complex. Moreover, when it comes to processing, as with most food industries, evidence indicates that the sanitary conditions of the seafood processing plant do correlate well with the microbial quality of the finished product (Phillips and Peeler, 1972; Surkiewicz et al., 1967; Duran et al., 1983; Wentz et al., 1985).

Work by Samuels et al. (1984) in finfish processing plants indicated that in some instances processing lines seem to reach a contamination "saturation point." Fish from the boats quickly contaminated the processing equipment (sorting tables, weigh scales, scalers, totes, knives, culling boards) with significant levels of psychrotrophs (1.0^6 colony forming units/in^2). The authors theorized that establishing an effective in-plant sanitation program could possibly lead to improved product quality and shelf life, but that effective sanitation would be contingent on decontaminating or reducing microbial loads on fish before they enter the processing lines. To accomplish this, they used a high-pressure wash on the whole fish to remove surface slime and its associated microflora. This treatment reduced psychrotrophic counts by 99%. Moreover, taste panel evaluations judged flounder fillets processed under the recommended procedures to have a shelf life of 11–12 days, as opposed to 7–8 days for fillets processed in the traditional manner.

Kosak and Toledo (1981) also investigated the effect of microbial decontamination on the storage stability of finfish. Chlorine dip was used for microbiological decontamination of the fish prior to packaging. The authors reported a doubling of shelf life by using the combined effects of a 3.5-min dip in a 1,000-μg/mL free chlorine solution followed by packaging under vacuum or in polyethylene bags. However, Samuels et al. (1984) found that dipping whole fish in a 200-ppm hypochlorite solution for 4 min followed by overwrapping in an oxygen-permeable film was only marginally advantageous over dipping in water.

Because of the unique nature of seafoods and seafood processing operations, it can be a difficult task to maintain extremely rigid standards with respect to microbial numbers on processing-plant equipment. One of the plants reported by Samuels et al. (1984) to be operating under sanitary conditions had psychrotroph concentrations on equipment surfaces ranging from 1.3×10^1 to 2.5×10^3 organisms/in^2. Because of gross contamination resulting from contact with

these heavily contaminated surfaces, there has been research regarding the benefits of delayed processing. Shaw et al. (1984), working with cod, found that maximum overall shelf life could be attained by delayed filleting, thereby reducing the time stored as fillets. The data indicated a 2-log difference in total aerobic plate count at 21°C from fillets cut from 1-day postmortem fish vs those from 7-day postmortem fish. The $\log_{10}$ counts were 7.3 and 5.3 cfu/g, respectively. (These fillets were from cod which had been eviscerated at sea).

Townley and Lanier (1981) looked at the possibility of delayed evisceration. Working with Atlantic croaker and grey trout, they reported no advantages to delayed processing. In fact, fish eviscerated immediately upon landing maintained class 1 quality 7–10 days longer than iced uneviscerated fish or iced fish eviscerated 3 days after harvest. Microbial populations were reported to remain lower in eviscerated fish, for both species, throughout a 2-week storage period (0–1°C with top icing).

Table 1—Examples of Different Parameters and Conditions used in evaluating shelf life

Parameter	Conditions reported in the literature
Storage temperatures	4°C, 3°C, 2°C, 1°C, ice, −1°C (salt ice)
End of shelf life	(a) Bacterial counts (1.0×10^6, 1.0×10^7) (b) Organoleptic (c) Chemical (trimethylamine, total volatile nitrogen) (d) Combination of a, b, and/or c
Bacterial plate count incubation temperatures	35°C, 30°C, 25°C, 20°C, 21°C

Preservatives

Given the perishable nature of seafoods, a satisfactory method for extending the shelf life of chilled products that ensures quality and a continuity of supply with a minimum of waste has been the ultimate goal. Research with certain preservatives to aid in this effort has met with varying degrees of success.

Sorbic acid and its potassium salt have been the subject of significant research activity in recent years. Fey and Regenstein (1982) reported potassium sorbate dips to be of minimal value in extending the shelf life of red hake and salmon. Chung and Lee (1981) indicated that inhibition of microbial growth by potassium sorbate was concentration dependent. With English sole, the inhibitory effects at 0.1% concentration were barely noticeable, while those at 1.0% concentration were quite pronounced. A delay in the microbial lag phase was reported as 1 day and 6 days, respectively. The researchers reported that the typical spoilage pattern was unchanged, with *Pseudomonas* spp. being the predominant spoilage flora for treated and untreated samples.

Bremner and Statham (1983) found significant shelf life extension for vacuum-packaged scallops treated with a 0.1% sorbate dip. The scallops, stored at 4°C, were acceptable for up to 28 days—an extension of 22 days beyond the untreated controls. The authors attributed this rather dramatic effect to the fact that the initial microflora, which was predominantly *Vibrio* spp., was quite susceptible to sorbate. In untreated vacuum-packaged and aerobically packaged scallops, *Vibrio* spp. were confirmed as the sole spoilage organism. In scallops treated with 0.1% sorbate and vacuum packaged, the population of spoilage organisms was heterogeneous, with a significant proportion of *Pseudomonas* spp. and *Aeromonas* spp.

Ward et al. (1982) reported that a 2.5% potassium sorbate dip had the potential to reduce bacterial numbers and extend shelf life of "good-quality" scallops. However, because of the nature of the scallop fishery and the extended cruise times, most of the scallops encountered in the study arrived at the dock with psychrotrophic counts of almost 1.0×10^6/g, and, as a result, the preservative was of little or no value.

Work by Statham et al. (1985) on the Australian fish morwong indicated that the most effective treatment for extending the shelf life of fillets stored at 4°C was to dip them in a combined solution of 1.2% potassium sorbate and 10% polyphosphate, followed by packaging in 100% CO_2. Miller and Brown (1984) reported that dipping in a combination of 1% potassium sorbate plus 5 ppm chlortetracycline, followed by vacuum packaging and storage at 2°C, was best at retaining the fresh properties of rockfish fillets after 14 days of storage.

Yet another attempt at chemical preservation of seafoods was reported by Wesley (1982). Whole flounder and flounder fillets were given an enzyme treatment consisting of glucose oxidase/catalase/glucose solution applied in three forms: as a dip, as enzymatic ice, and immobilized in algin blankets. The results indicated that untreated controls were acceptable for 8 days, while treated samples remained acceptable for 15. Shaw et al. (1986) reported on their work with glucose oxidase dips and gluconic acid dips on the preservation of cod fillets. Their results indicated only marginal differences in the acceptability of either treatment over that of controls. Consequently, the researchers felt that these treatment methodologies have little potential.

Packaging

From a review of the literature, it is apparent that there has been tremendous interest in packaging as a means of extending the shelf life of muscle protein foods, especially seafood. Of particular interest have been the areas of modified and controlled atmospheres and vacuum packaging.

Packaging of products in a modified gas atmosphere involves the replacement of air by other gases, usually CO_2, N_2, and O_2, alone or in combination. Research on a variety of seafood products indicates that the inhibitory effect of CO_2 on the psychrotrophic, aerobic, Gram-negative spoilage bacteria is proportional to the CO_2 tension in the packages, with maximum inhibition of growth achieved with 100% CO_2 (Lannelongue et al., 1982a, b; Stenstrom, 1985; Barnett et al., 1982; Layrisse and Matches, 1984). The principal effect of CO_2 on inhibiting the growth of spoilage bacteria is an extension in the lag phase and a reduced growth rate in the logarithmic phase (Gray et al., 1983). However, the mechanism whereby CO_2 inhibits or delays bacterial growth remains the object of study and debate. Finne (1982) and Daniels et al. (1985) discussed several theories in their review articles.

Packaging of seafoods in high concentrations of CO_2 has some technical disadvantages: (a) CO_2 dissolves into the fish liquids, causing deformation of the package, and (b) discoloration of highly pigmented fish occurs (Stenstrom, 1985). For these reasons, other gases such as O_2 or N_2 are used to replace part of the CO_2. A wide variety of gas mixtures have been tried on a host of different products, and, as might be expected, there have been differences in results and interpretations. A prime example of this would be a comparison of work reported by Woyewoda et al. (1984) and Stenstrom (1985) on cod fillets. Woyewoda et al. used both modified and controlled atmospheres of 60% CO_2/40% air and a storage temperature of 1°C. Their results indicated that, overall, total aerobic plate counts for cod fillets stored in modified and controlled atmospheres were no different from their respective controls. All controls were considered spoiled by day 9, while packaged fish were unacceptable by day 12. In summary, the researchers felt that there was "no overall superiority for controlled or modified packaging under the conditions studied." On the other hand, Stenstrom packaged fillets in a modified atmosphere of 50% CO_2/50% O_2 and stored them at 2°C. Her work indicated an acceptable shelf life of 14 days, and thus she concluded that the method was "sufficiently efficient to prolong the shelf life of cod fillets in the industry." In a review by Statham (1984), shelf life extension obtained using modified atmospheres of various

gas mixtures, products, and storage temperatures ranged from 50 to 200%.

Standard Conditions Needed

When reviewing the literature associated with seafoods, particularly those papers on microbiology and its relationship to quality and shelf life, there are *apparent* contradictions. The word "apparent" is stressed because it is often difficult to determine if the contradictions are associated with species, methodology, or both. Compositional differences associated with species as well as differences associated with the native microflora can result in different spoilage patterns and rates. However, these differences are difficult to detect because of different control methodologies. Examples of differences reported in the literature are shown in Table 1.

While on the surface these differences may seem trivial, I would suspect that these, as well as other differences not mentioned, are some of the reasons why *apparent* contradictions are encountered. Perhaps it is time researchers consider a "standard" which could serve as a comparative control among food technologists with research interest in seafoods.

References

Ampola, V.G. 1980. The quality of squid held in chilled seawater versus conventional shipboard handling. Mar. Fish. Rev. 43(4): 7-4.

Barile, L.E., Milla, A.D., Reilly, A., and Villadsen, A. 1985a. Spoilage Patterns of Mackerel *(Rastrelliger faughni* Matsui). 1. Delays in icing. ASEAN Food J. 1(2): 70.

Barile, L.E., Milla, A.D., Reilly, A., and Villadsen, A. 1985b. Spoilage patterns of mackerel *(Rastrelliger faughni* Matsui). 2. Mesophilic and psychrophilic spoilage. ASEAN Food J. 1(3).

Barnett, H.J., Nelson, R.W., Hunter, P.J., Bauer, S., and Groniger, H. 1971. Studies on the use of carbon dioxide dissolved in refrigerated brine for the preservation of whole fish. Fish. Bull. 69: 433.

Barnett, H.J., Stone, F.E., Roberts, G.C., Hunter, P.J., Nelson, R.W., and Kwok, J. 1982. A study in the use of a high concentration of CO_2 in a modified atmosphere to preserve fresh salmon. Mar. Fish. Rev. 44(3): 7.

Borgstrom, G. 1961. "Fish as Food," Vol. 1. Academic Press, New York.

Bremner, H.A. and Statham, J.A. 1983. Effect of potassium sorbate on refrigerated storage on vacuum packed scallops. J. Food Sci. 48: 1042.

Bronstein, M.N., Price, R.J., Strangs, E.M., Melvin, E.F., Dewees, C.M., and Wyatt, B.B. 1985. Storage of dressed chinook salmon, *Oncorhynchus tshawytscha*, in refrigerated freshwater, diluted seawater, seawater, and in ice. Mar. Fish. Rev. 47(1): 68.

Bullard, F.A. and Collins, J. 1978. Physical and chemical changes of pink shrimp, *Pandalus borealis*, held in carbon dioxide modified refrigerated seawater compared with pink shrimp held in ice. Fish Bull. 76: 73.

Chinivasagam, H.N. and Vidanapathirana, G.S. 1986. Quality changes and bacterial flora associated with trench sardines *(Amblygaster sirm)* under delayed icing conditions. FAO Fisheries Rept. 317. Food and Agric. Org., Rome, Italy.

Chung, Y. and Lee, J.S. 1981. Inhibition of microbial growth in English sole *(Parophrys retulus)*. J. Food Protect. 44: 66.

Daniels, J.A., Krishnamurthi, R., and Rizvi, S.S. 1985. A review of effects of carbon dioxide on microbial growth and food quality. J. Food Protect. 48: 532.

DeSilva, G.T.K. 1978. Storage life of Soora puraw *(Selas leptolepsis)* with delayed icing of 9 and 12 hours. Cited in Chinivasagam and Vidanapathirana (1986).

Disney, J.G. 1986. The spoilage of fish in the tropics. In "Proceedings of the First Annual Tropical and Subtropical Fisheries Technology Conference," ed. B.F. Cobb and A.B. Stockton, Vol., 1, p. 23. Texas A&M Univ. Sea Grant, College Station, Tex.

Duran, A.P., Wentz, B.A., Lanier, J.M., McClure, F.D., Schwab, A.H., Swartzentruber, A., Barnard, R.J., and Read, R.B. Jr. 1983. Microbiological quality of breaded shrimp during processing. J. Food Protect. 46: 974.

FAO. 1973. Code of practice for fresh fish. FAO Fisheries Circ. C318. Food and Agric. Org. of the United Nations, Rome, Italy.

Fey, M.S. and Regenstein, J.M. 1982. Extending shelf-life of fresh wet red hake and salmon using CO_2-O_2 modified atmosphere and potassium sorbate ice at 1°C. J. Food Sci. 47: 1048.

Finne, G. 1982. Modified- and controlled-atmosphere storage of muscle foods. Food Technol. 36(2): 128.

Gray, J.R.H., Hoover, D.G., and Muir, A.M. 1983. Attenuation of microbial growth of modified atmosphere-packaged fish. J. Food Protect. 46(7): 610.

Holston, J. and Slavin, J.W. 1965. Technological problems in the preservation of fish, iced fish requiring more knowledge from fundamental research. In "Technology of Fish Utilization," ed. R. Kreuzer, p. 41. Fishing News (Books) Ltd., London.

Huss, H.H., Dalsgaard, D., Hansen, L., Ladefoged, H., Pedersen, A., and Zittan, L. 1974. The influence of hygiene in catch handling on the storage life of iced cod and plaice. J. Food Technol. 9: 213.

Jayaweera, V. 1980. Storage life of silverbelly *(Leiognathus* spp.) with delayed icing. Bull. Fish. Res. Sta., Sri Lanka 30(1-2): 53.

Kosak, P.H. and Toledo, R.T. 1981. Effects of microbiological decontamination on the storage stability of fresh fish. J. Food Sci. 46: 1012.

Lannelongue, M., Hanna, M.O., Finne, G., Nickelson, R., and Vanderzant, C. 1982a. Storage characteristics of finfish fillets *(Archosargus probatocephalus)* packaged in modified gas atmospheres containing carbon dioxide. J. Food Protect. 45: 440.

Lannelongue, M., Finne, G., Hanna, M.O., Nickelson, R., and Vanderzant, C. 1982b. Microbiological and chemical changes during storage of swordfish *(Xiphias gladius)* steaks in retail packages containing CO_2-enriched atmospheres. J. Food Protect. 45: 1197.

Layrisse, M.E. and Matches, J.R. 1984. Microbiological and chemical changes of spotted shrimp *(Pandalus platyceros)* stored under modified atmospheres. J. Food Protect. 47: 453.

Lee, J.S. and Kolbe, E. 1982. Microbiological profile of Pacific shrimp, *Pandalus jordani*, stowed under refrigerated seawater spray. Mar. Fish. Rev. 44(3): 12.

Lemon, D.W. and Regier, L.W. 1977. Holding of Atlantic mackerel *(Scomber scombrus)* in refrigerated sea water. J. Fish. Res. Board Can. 34: 439.

Lima dos Santos, C.A.M. 1981. The storage of tropical fish in ice—A review. Tropical Sci. 23(2): 97.

Liston, J. 1955. A quantitative and qualitative study of the bacterial flora of skate and lemon sole trawled in the North Sea. Ph.D. thesis, Aberdeen Univ., Aberdeen, Scotland. Cited in Borgstrom (1961), p. 495.

Longard, A.A. and Regier, L.W. 1974. Color and some compositional changes in ocean perch *(Sebastes marinus)* held in refrigerated sea water with and without carbon dioxide. J. Fish. Res. Board Can. 31: 456.

Martin, R.E., Gray, R.J.H., and Pierson, M.D. 1978. Quality assessment of fresh fish and the role of the naturally occurring microflora. Food Technol. 32(5): 188.

Mayer, B., Samuels, R., Flick, G., Hackney, C., Rippen, T., Soul, D., Sanders, L., Coale, C., Dupaul, W., Smith, C., and Clusman, A. 1986. A seafood quality program for the mid-Atlantic region, Part II. A report submitted to the Mid-Atlantic Fisheries Development Foundation. Virginia Polytechnic Inst. and State Univ., Sea Grant, Blacksburg.

Miller, S.A. and Brown, W.D. 1984. Effectiveness of chlortetracycline in combination with potassium sorbate or tetrasodium ethylenediaminetetraacetate for preservation of vacuum packed rockfish fillets. J. Food Sci. 49: 188.

Nelson, R.W. and Barnett, H.J. 1973. Fish preservation in refrigerated seawater modified with carbon dioxide. Proc. 13th Intl. Cong. Refrig. 3: 57.

Nickelson, R. and Vanderzant, C.V. 1976. Bacteriology of shrimp. Paper presented at 1st Annual Tropical and Subtropical Fisheries Technology Conf., Corpus Christi, Tex., March 8-10. Texas A&M Univ., College Station.

Otwell, W.S. 1986. Why is seafood quality less regulated than meat or poultry? In "Water Log," ed. C. Jarman and D. Conner, Vol. 6, p. 3. Mississippi-Alabama Sea Grant Consortium, University, Miss.

Phillips, P.A. and Peeler, J.T. 1972. Bacteriological survey of the blue crab industry. Appl. Microbiol. 24: 958.

Poulter, R.G., Curran, C.A., and Disney, J.G. 1981. Chill storage of tropical and temperate water fish—Differences and similarities. Advances in the refrigerated treatment of fish, especially underutilized species. Bull. Intl. Inst. Refrig. 49: 111.

Ravesi, E.M., Licciardello, J.J., Tuhkunen, B.E., and Lundstrom, R.C. 1985. The effect of handling or processing treatments on storage characteristics of fresh spiny dogfish, *Squalus acanthias*. Mar. Fish. Rev. 47(1): 48.

Reppond, K.D. and Collins, J. 1983. Pacific cod *(Gadus macrocephalus)*: Change in sensory and chemical properties when held in ice and in CO_2 modified refrigerated seawater. J. Food Sci. 48: 1552.

Reppond, K.D., Bullard, F.A., and Collin, J. 1979. Walleye pollock, *Theragra chalcogramma*: Physical, chemical and sensory changes when held in ice and in carbon dioxide modified refrigerated seawater. Fish Bull. 77: 481.

Reppond, K.D., Collins, J., and Markey, D. 1985. Walleye pollock *(Theragra chalcogramma)*: Changes in quality when held in ice, slush-ice, refrigerated seawater, and CO_2-modified refrigerated seawater then stored as block of fillets at −18°C. J. Food Sci. 50: 985.

Roach, S.W., Tarr, H.L.A., and Tomlinson, N. 1967. Chilling and

freezing salmon and tuna in refrigerated sea water. Bull. 160. Fish. Res. Bull. Can., Ottawa.
Samuels, R.D., DeFeo, A., Flick, G.J., Ward, D.R., Rippen, T., Riggins, J.K., Coale, C., and Smith, C. 1984. Demonstration of a quality maintenance program for fresh fish products, A report submitted to Mid-Atlantic Fisheries Development Foundation. Virginia Polytechnic Inst. and State Univ., Sea Grant, VPI-SG-84-04R, Blacksburg.
Shaw, S.J., Bligh, E.G., and Woyewoda, A.D. 1984. Effect of delayed filleting on quality of cod flesh. J. Food Sci. 49: 979.
Shaw, S.J., Bligh, E.G., and Woyewoda, A.D. 1986. Spoilage pattern of Atlantic cod fillets treated with glucose oxidase/gluconic acid. Can. Inst. Food Sci. Technol. J. 19: 3.
Shewan, J.M. 1949. Some bacteriological aspects of handling, processing and distribution of fish. J. Royal Sanit. Inst. 59: 394.
Shewan, J.M. 1353. Some recent progress in the bacteriology of marine fish. Atti. Congr. Intern. Microbiol. Roma 7. p 361. Cited in Borgstrom (1961), p. 495.
Shewan, J.M. 1961. The microbiology of sea-water fish. In Borgstrom (1961), p. 487.
Shewan, J.M. 1977. The bacteriology of fresh and spoiling fish and the biochemical changes induced by bacterial action. In "Proceedings of the Conference on Handling, Processing, and Marketing of Tropical Fish," p. 51. Tropical Products Inst., London.
Stansby, M.E. and Lemon, J.M. 1941. Studies on the handling of fresh mackerel *(Scomber scombus)*. Res. Rept. 1, U.S. Fish and Wildlife Serv. Washington, D.C.
Statham, J.A. 1984. Modified atmosphere storage of fisheries products: The state of the art. Food Technol. Australia 36: 233.
Statham, J.A., Bremner, H.A., and Quarmby, A.R. 1985. Storage of morwong (*Nemadactylus macropterus* Bloch and Schneider) in combinations of polyphosphate, potassium sorbate and carbon dioxide at 4°C. J. Food Sci. 50: 1580.
Stenstrom, I. 1985. Microbial flora of cod fillets *(Gadus morhua)* stored at 2°C in different mixtures of carbon dioxide and nitrogen/oxygen. J. Food Protect. 48: 585.
Sumner, J.L., Gorczyca, E., Cohen, D., and Brady, P. 1984. Do fish from tropical waters spoil less rapidly in ice than fish from temperate waters? Food Technol. Australia 36: 328.
Surkiewicz, B.F., Hyndman, J.B., and Yancy, M.V. 1967. Bacteriological survey of the frozen prepared food industry. II. Frozen breaded raw shrimp. Appl. Microbiol. 15: 1.
Townley, R.R. and Lanier, T.C. 1981. Effect of early evisceration on the keeping quality of Atlantic croaker *(Micropogon undulatus)* and grey trout *(Cynoscion regalis)* as determined by subjective and objective methodology. J. Food Sci. 46: 863.
Ward, D.R., Butler, P.F., Hopson, D.J., and Daniels, J.A. 1982. Shelf life extension of fresh finfish and scallops with potassium sorbate as a function of concentration and method of application. Presented at 42nd Annual Meeting, Inst. of Food Technologists, Las Vegas, Nev., June 22–25.
Wentz, B.A., Duran, A.P. Swartzentruber, A., Schwab, A.H., McClure, F.D., Archer, D., and Read, R.B. Jr. 1985. Microbiological quality of crabmeat during processing. J. Food Protect. 48: 44.
Wesley, P. 1982. Glucose oxidase treatment prolongs shelf-life of fresh seafood. Food Dev. Jan., p. 36.
Woyewoda, A.D., Bligh, E.G., and Shaw, S.J. 1984. Controlled and modified atmosphere storage of cod fillets. Can. Inst. Food. Sci. Technol. J. 17(1): 24.

Based on a paper presented during the IFT Food Microbiology Division/Seafood Products Technology Group program, "Microbiology of Marine Food Products," at the Annual Meeting of the Institute of Food Technologists, Las Vegas, Nev., June 16–19, 1987.

—Edited by Neil H. Mermelstein, Senior Associate Editor

MARINE TOXINS OF MICROBIAL ORIGIN

STEVE L. TAYLOR

□ TOXINS elaborated by microorganisms of marine origin or microorganisms proliferating on marine foods are responsible for a substantial number of cases of foodborne disease. These toxins can be produced by algae (ciguatera toxins, saxitoxins, brevetoxins, dinophysistoxins) or bacteria (histamine). Marine fish are primarily implicated in some of the illnesses associated with these toxins, such as ciguatera poisoning and scombroid fish (histamine) poisoning. Shellfish are implicated in other illnesses, such as paralytic shellfish poisoning, neurotoxic shellfish poisoning, and diarrhetic shellfish poisoning.

Table 1 provides a list of the diseases, the implicated marine foods, the toxin-producing microorganisms, and the number of outbreaks and cases of each disease in the United States that were reported to the Centers for Disease Control during 1977–81. While the incidence of these foodborne diseases does not approach that related to *Salmonella* or the staphylococcal enterotoxins, these illnesses are among the most important foodborne diseases of chemical etiology in the U.S. This review will focus on the distinguishing features of these particular illnesses.

Scombroid Fish (Histamine) Poisoning

As indicated in Table 1, scombroid fish poisoning occurs rather frequently in the U.S. This illness has historically been associated with the ingestion of spoiled fish belonging to the scombroid groups, *Scombridae* (tuna, mackerel, bonito, Spanish mackerel) and *Scomberesocidae* (saury). However, other types of fish are also commonly implicated in scombroid fish poisoning; these include mahi-mahi, bluefish, jack mackerel, yellowtail, amberjack, herrings, sardines, and anchovies. Thus, the term scombroid fish poisoning is actually a misnomer, because of the frequent involvement of nonscombroid fish in the disease. The preferred term would be histamine poisoning, since this illness is caused by ingestion of hazardous levels of histamine that have accumulated during the spoilage of the implicated fish.

Histamine poisoning is a worldwide problem occurring rather frequently in any country where consumers ingest any of the fish listed above (Taylor, 1985a; 1986). The U.S., Japan, and Great Britain have reported the greatest number of histamine poisoning incidents (Taylor, 1986). However, the illness probably occurs in many countries that simply do not report foodborne illnesses. Since histamine poisoning is a rather mild illness, it is probably not completely reported in any country.

Histamine poisoning is a chemical intoxication resulting from the ingestion of foods that contain unusually high levels of histamine. The incubation period between ingestion of the incriminated fish and the onset of symptoms is rather short, ranging from a few minutes to a few hours. The duration of the illness is also rather short. Symptoms usually subside spontaneously within a few hours. The typical symptoms of histamine poisoning are listed in Table 2. The fact that these symptoms can also occur with many other illnesses leads to a failure to correctly diagnose histamine poisoning in many cases. The most commonly encountered symptoms are tingling and burning sensations around the mouth, gastrointestinal complaints, and a rash with itching. A case definition for histamine poisoning should include the rapid onset of the types of symptoms described above after ingestion of a food that has been implicated in this foodborne disease. However, the outbreak cannot be confirmed as histamine poisoning without detection of high levels of histamine in the implicated food.

The disease is often diagnostically confused with food allergy. This confusion is understandable, since histamine is a primary in-vivo mediator of allergic disease (Taylor, 1985b; 1987). Outbreaks of histamine poisoning can be easily distinguished from cases of food allergy, however: The patients will usually not have any prior history of adverse reactions to the implicated food. In group outbreaks, the attack rate will approach 100%, a situation that would never occur with food allergies. Finally, analysis of the implicated food will frequently reveal high levels of histamine. While allergic reactions to fish occur with some frequency, the likelihood of histamine poisoning is much greater with tuna, mackerel, and mahi-mahi than are the chances of an allergic reaction to these particular species.

Histamine is formed in foods by bacteria that possess the enzyme histidine decarboxylase. This enzyme acts on the amino acid L-histidine. The fish frequently involved in histamine poisoning characteristically have high levels of free L-histidine in their muscle tissues. Further histamine may be released by proteolytic action, either autolytic or bacterial. Histidine decarboxylase is not widely distributed among bacteria. In fish, the most important histamine-forming bacteria are *Morganella morganii, Klebsiella pneumoniae,* and perhaps a few other enteric bacteria (Taylor, 1986). Some lactobacilli also produce histamine at appreciable rates, but these bacteria would only be expected to proliferate in fermented fish (Taylor, 1986). Fermented fish can contain high levels of histamine (Taylor, 1985a). Bacterial histamine formation can usually be controlled by proper storage of fish at low temperatures (Taylor, 1986).

The evidence implicating histamine as the causative agent of this foodborne disease is compelling. High levels of histamine have often been found in the implicated fish, when appropriate samples were available. The symptoms noted in the outbreaks are consistent with histamine as the causative agent. However, the most convincing evidence is the efficacy of antihistamines in counteracting the symptoms observed in these cases.

Rather high levels of histamine in fish are required to induce adverse reactions. Currently, the Food and Drug Administration has a hazard action level for histamine in tuna of 50 mg/100 g (500 ppm) of fish. A level of 20 mg/100 g (200 ppm) of tuna is considered evidence of decomposition. Regulatory limits have not been set for other fish that are commonly involved in episodes of histamine poisoning. However, many foods will contain small amounts of histamine, particularly if these foods are fermented. These small amounts of histamine do not represent any hazard to consumers. Histamine represents a problem only when levels approach or exceed 50 mg/100 g (500 ppm) in fish and other foods.

Some evidence suggests that certain substances in spoiled fish may potentiate the toxicity of histamine (Hui and Taylor, 1985; Lyons et al., 1983; Taylor et al., 1984). Oral administration of histamine alone to humans or animals does not provoke adverse reactions until very high doses of 150–200 mg are reached (Motil and Scrimshaw, 1979; Taylor, 1986). Thus, histamine appears to be more toxic when ingested with spoiled fish. The existence of potentiators of

The author is Head, Dept. of Food Science and Technology, University of Nebraska, Filley Hall, Lincoln, NE 68583-0919

Table 1—**Foodborne Diseases Caused by Marine Microbial Toxins**

Disease	Seafoods implicated	Toxin-producing microorganism	Disease incidence in the U.S., 1977–81: No. of outbreaks	Disease incidence in the U.S., 1977–81: No. of cases
Bacteria-associated				
Scombroid fish poisoning	Scombroid and other fish	*Morganella morganii, Klebsiella pneumoniae,* and others	68	461
Algae-associated				
Ciguatera poisoning	Reef fishes, including barracuda, grouper, red snapper, sea basses	*Gambierdiscus toxicus, Prorocentrum concavum,* and others	70	367
Paralytic shellfish poisoning	Shellfish, including clams, mussels, cockles, scallops	*Gonyaulax catenella, G. tamarensis,* and others	9	126
Neurotoxic shellfish poisoning	Shellfish	*Ptychodiscus brevis*	0	0
Diarrhetic shellfish poisoning	Shellfish	*Dinophysis fortii*	0	0

Table 2—**Symptoms of Histamine Poisoning**

Type	Symptoms
Gastrointestinal	Nausea, vomiting, diarrhea, cramping
Neurological	Headache, palpitations, flushing, tingling, burning, itching
Hemodynamic	Hypotension
Cutaneous	Rash, urticaria (hives), edema, localized inflammation

histamine toxicity in spoiled fish would explain this observation. Considerable in-vitro evidence implicates other putrefactive amines as potentiators of histamine toxicity (Taylor et al., 1984; Taylor, 1986). Cadaverine and putrescine enhance the lethality of orally administered histamine in guinea pigs (Bjeldanes et al., 1978; Parrot and Nicot, 1966). Presumably, these putrefactive amines interfere with the detoxification of histamine by inhibiting enzymes that are responsible for its detoxification (Lyons et al., 1983; Hui and Taylor, 1985). However, these putrefactive amines only potentiate the toxicity of histamine or prolong its half-life in vivo when a major excess of these amines exists (Hui and Taylor, 1985; Taylor, 1986). In spoiled fish, these amines do not usually exist in concentrations greater than that observed for histamine. Thus, the role of potentiation in histamine poisoning remains unclear.

Histamine poisoning can be prevented by a variety of measures (Taylor, 1986). With fish, the typical control measure is to hold the fish at low storage temperatures to prevent bacterial growth and histamine formation. Hygienic practices to prevent the contamination of fish with histamine-producing bacteria are not often employed. Histamine-producing bacteria are usually considered to be part of the normal microflora of the gut, skin, or gills of tuna and other involved species. However, histamine-producing enteric bacteria would not necessarily be expected to proliferate under such conditions (Taylor, 1986).

Post-catching contamination may be a very important source of histamine-producing bacteria (Taylor and Speckhard, 1983). Contamination of fish with histamine-producing bacteria in a restaurant situation has been demonstrated to be an important factor in at least one outbreak of histamine poisoning (Yamani et al., 1981). Good quality assurance programs for the fish typically involved in histamine poisoning should include analysis for histamine. Several rapid methods allow screening of a large number of samples (Taylor, 1986).

Ciguatera Poisoning

Ciguatera poisoning results from the ingestion of fish that have become toxic by feeding on toxic dinoflagellates, which are microscopic marine planktonic algae. More than 400 species of finfish have been implicated in ciguatera poisoning (Randall, 1980). The implicated fish are usually bottom feeders or reef fishes (Lewis, 1984; Randall, 1980). Larger fish are more frequently implicated than smaller fish of the same species. Among the more commonly implicated species are grouper, barracuda, red snapper, and sea basses. The internal organs of the fish—the liver, intestines, roe, and gonads—are more toxic than the more commonly consumed muscle tissues (Hokama and Miyahara, 1986).

Ciguatera poisoning can occur in any tropical or subtropical region, especially where reef fishes are a common dietary component (Lewis, 1984). In the U.S., ciguatera poisoning occurs most frequently in Puerto Rico, the Virgin Islands, Hawaii, and Florida (Lewis, 1984; Ragelis, 1984b). While the reported incidence of ciguatera poisoning is only a few dozen cases/yr in the U.S. (Table 1), Ragelis (1984b) estimated that the worldwide incidence of ciguatera poisoning may approach 50,000 cases/yr, including 2,000 cases/yr in the U.S. The outbreaks are not always reported to CDC. The prevalence in Dade County, Fla., has been estimated at 0.5 cases/1,000 population (Lawrence et al., 1980). The prevalence among the local population in St. Thomas, Virgin Islands, has been estimated at 27 cases/1,000 population (McMillan et al., 1980).

The microbial toxins associated with ciguatera poisoning primarily affect the gastrointestinal and neurological systems (Morris et al., 1982; Ragelis, 1984b). The onset time for this illness is usually a few hours. A wide variety of symptoms can occur. The moderate-to-severe gastrointestinal manifestations of relatively short duration include abdominal pain, nausea, vomiting, and diarrhea of short duration. Moderate-to-severe neurological disorders that may persist for varying periods of time up to several months can occur. The neurological symptoms include muscular aches; tingling and numbness of the lips, tongue, and perioral region; metallic taste; dryness of the mouth; anxiety; malaise; prostration; dizziness; cyanosis; chills; profuse sweating; dilated eyes and blurred vision; temporary blindness; paralysis; and death. Death due to respiratory paralysis occurs rarely among those individuals who receive prompt medical attention. No antidote exists for ciguatera poisoning. Artificial respiration is the treatment of choice in severe cases where respiratory paralysis occurs. The prognosis for recovery is good if the patient survives the first 24 hr. However, the recovery period can be rather prolonged in some cases.

The genesis of ciguatera poisoning was a mystery until 1977, when the first report appeared of a toxic dinoflagellate

associated with this illness (Bagnis et al., 1980; Yasumoto et al., 1977). Since the initial identification of this toxic dinoflagellate, *Gambierdiscus toxicus*, in the South Pacific, other toxic dinoflagellates have also been associated with ciguatera poisoning. In the Caribbean area, the primary toxic species identified thus far are *G. toxicus*, *Prorocentrum concavum*, and *P. mexicana* (Tindall et al., 1984). The identification of the toxic dinoflagellates involved in ciguatera poisoning remains an active area of research, and it is likely that additional species will be identified.

The toxic dinoflagellates are able to proliferate, or bloom, under certain conditions. Apparently, the warm, shallow waters of reef areas are ideal for such blooms. Some fish feed on planktonic algae and will become toxic when a toxin-producing species is involved in the bloom. Larger fish can be affected by ingesting the smaller fish; the toxins can be assimilated through the food chain (Randall, 1980). The feeding habits of the fish are important in determining their degree of toxicity (Randall, 1980). The dinoflagellate blooms in these temperate reef areas can be quite prolonged, and in some cases certain species of fish must be permanently avoided (Randall, 1980). Some fish may be able to clear the toxins from their systems if the bloom ceases. Larger fish, because of their greater mass and slower growth, probably clear the toxins more slowly.

Several neurotoxins have been isolated from ciguatoxic fishes or *G. toxicus* growing in culture (Dickey et al., 1984; Legrand and Bagnis, 1984; Miller et al., 1984; Scheuer et al., 1967). The major neurotoxin isolated from ciguatoxic fishes is ciguatoxin, a lipid-soluble polyether compound of uncertain structure and a molecular weight of approximately 1,100. The mechanism of action of ciguatoxin is unknown, but it may act as an ionophoric substance in nerve membranes and thus disturb ion fluxes across those membranes. Cultures of *G. toxicus* yield three lipid-soluble toxins. One of these toxins is probably identical to ciguatoxin. A water-soluble toxin, known as maitotoxin, has also been isolated from ciguatoxic fishes and cultures of *G. toxicus*. The structure and mechanism of action of this neurotoxin are not known.

Control measures for ciguatera poisoning do not exist. No reliable, widely available method exists for the detection of the toxins or ciguatoxic fish. Thus, no monitoring program has been established. The risk of ciguatera poisoning can be lowered somewhat by avoiding unusually large specimens of the reef fishes and excluding the internal organs and roe of these fishes from the diet.

Paralytic Shellfish Poisoning

Paralytic shellfish poisoning is associated with the ingestion of mussels, clams, cockles, or scallops that have fed on toxic species of dinoflagellates. Fewer cases of paralytic shellfish poisoning have occurred in the U.S. in recent years, thanks in part to a monitoring and quarantine program. However, paralytic shellfish poisoning is a very serious illness with a high fatality rate.

Many of the species of shellfish implicated in paralytic shellfish poisoning are safe to consume except during those times when they are feeding on the toxic dinoflagellates. Thus, paralytic shellfish poisoning tends to occur sporadically (Schantz, 1984). The dinoflagellates bloom as a function of the temperature of the water, light, salinity, presence of nutrients and trace minerals, runoff, winds, and other environmental conditions (Yentsch, 1984). Water temperature is a particularly critical environmental factor influencing the development of blooms. In most cases, the water temperature must be 5–8°C. As the populations of the toxic dinoflagellates increase during one of these blooms, the shellfish in the area begin to become toxic. The dinoflagellates often exist as cysts buried in the upper layers of sediment on the ocean floor (Anderson, 1984). The cysts serve as the seed population for blooms, which will occur when the environmental conditions are favorable. The blooms persist until unfavorable environmental conditions develop and force the dinoflagellates to return to the cyst stage. Shellfish tend to accumulate in shallow waters close to shore, and dinoflagellate blooms often occur in these same types of locations. The temperature of deep ocean waters holds rather constant at 4°C, which is too cold to encourage dinoflagellate blooms.

Several dinoflagellates are involved in paralytic shellfish poisoning. In the U.S., *Gonyaulax catenella* and *G. tamarensis* are the most commonly implicated species (Taylor, 1984). *G. catenella* is responsible for most of the toxic blooms on the West Coast of the U.S., while *G. tamarensis* is responsible for the toxic blooms occurring on the East Coast of the U.S.

The toxins produced by these dinoflagellates tend to persist in shellfish for varying periods of time, depending upon the shellfish and the tissue involved (Schantz, 1973). Some shellfish can clear the toxins very quickly and are toxic only during the periods of the actual blooms. Other shellfish species, such as the butter clams in the Bay of Alaska, retain the toxins for years (Schantz, 1984); these butter clams are never safe to consume. In general, the dark meat or internal organs of any shellfish species tend to accumulate more toxin than the muscle tissues (Schantz, 1984). Therefore, the white meat is sometimes safe to eat, while the dark meat is still hazardous. With scallops, the only cases of paralytic shellfish poisoning have occurred from consumption of the viscera (Jamieson and Chandler, 1983). With clams and mussels, the white meat can also be toxic on occasion, although the dark meat is likely to be more hazardous.

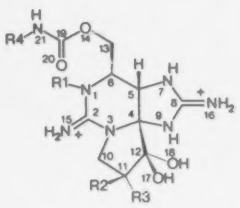
Paralytic shellfish poisoning is a neurological disorder (Schantz, 1973). The onset time is usually less than 1 hr. The duration is variable, but symptoms usually subside within a few days. The symptoms include tingling, burning, and numbness of the lips and fingertips; ataxia; giddiness; staggering; drowsiness; dry throat and skin; incoherent speech; aphasia (loss of ability to use or understand speech); rash; fever; peripheral and respiratory paralysis; and death. Death usually occurs within the first 24 hr. If the patient survives the first 24 hr, the prognosis for a complete recovery is good. No antidote exists for paralytic shellfish poisoning. Artificial respiration is usually provided in cases where paralysis occurs.

The toxins produced by these dinoflagellates are known collectively as saxitoxins (Hall and Reichardt, 1984). The structures of the parent molecule, saxitoxin, and 11 other derivatives are shown in Figure 1. Saxitoxin was the first of these toxins to be isolated from poisonous shellfish. The other 11 saxitoxins have also been found in toxic shellfish. Most toxic shellfish actually contain a mixture of these toxins.

The toxicity of 8 of the 12 saxitoxins is indicated in Figure 2. Mouse units are a measure of the lethality of these toxins to mice under standardized conditions (AOAC, 1984); one mouse unit is the amount of toxin injected intraperitoneally that is needed to kill a 20-g mouse in 15 min. Saxitoxin (STX), neosaxitoxin (NEO), which has a hydroxyl group at the C-7 position, and the gonyautoxins (GTX2 and GTX3), which are 11-hydroxy-saxitoxin sulfate derivatives, are the most toxic of the saxitoxins (Hall and Reichardt, 1984). STX and NEO have toxicities in the vicinity of 2,000 mouse units/micromole. From an investigation of outbreaks of paralytic shellfish poisoning, human illness is known to occur following the ingestion of about 600 mouse units of these toxins, while death will occur after ingestion of 3,000–5,000 mouse units (Bond and Medcof, 1957).

The saxitoxins act by binding to the sodium channels in nerve cell membranes and blocking nerve transmission (Ritchie and Rogart, 1977). The guanidinium group at positions C-7, C-8, and C-9 and the hydroxyl group at the C-12 position are essential for binding. Sodium entry through the nerve cell membrane is essential for nerve transmission.

Paralytic shellfish poisoning cannot be entirely controlled or prevented. The major preventive measure is inspection of shellfish from various shellfish beds and analysis for the toxins. The mouse bioassay is usually used for this purpose. If the shellfish are found to contain hazardous levels of the saxitoxins, commercial harvesting is halted and the shellfish beds are quarantined. Further testing will reveal when the shellfish harvest can be resumed. Signs are posted to alert recreational harvesters to avoid shellfish from quarantined areas. A quarantine is enacted when the toxin level in the shellfish reaches 400 mouse units/100 g of shellfish or 80 μg of saxitoxin/kg of shellfish. Consumers should also avoid eating the dark meat of the shellfish, since it often contains more of the toxins.



	R1	R2	R3	R4	
1	H	H	H	H	STX
2	H	H	H	SO_3^-	B1
3	H	H	OSO_3^-	H	GTX 2
4	H	H	OSO_3^-	SO_3^-	C1
5	H	OSO_3^-	H	H	GTX 3
6	H	OSO_3^-	H	SO_3^-	C2
7	OH	H	H	H	NEO
8	OH	H	H	SO_3^-	B2
9	OH	H	OSO_3^-	H	GTX 1
10	OH	H	OSO_3^-	SO_3^-	C3
11	OH	OSO_3^-	H	H	GTX 4
12	OH	OSO_3^-	H	SO_3^-	C4

Fig. 1—**Structure of the 12 Saxitoxins** *produced by Gonyaulax species. From Hall and Reichardt (1984)*

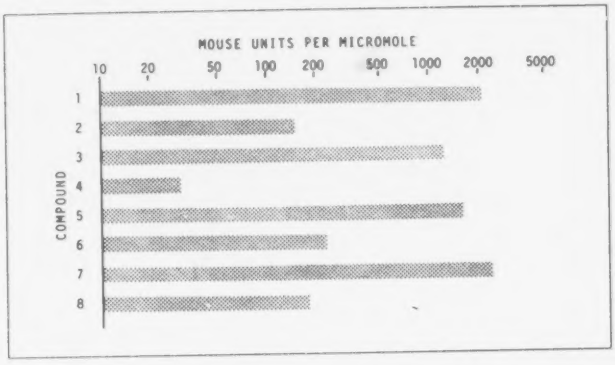


Fig. 2—**Comparative Toxicities** *of 8 saxitoxins (compounds 1-8 in Fig. 1). From Hall and Reichardt (1984)*

Neurotoxic Shellfish Poisoning

The marine dinoflagellate *Ptychodiscus brevis*, previously known as *Gymnodinium breve*, is the causative microorganism in red tides, and it also produces the toxins associated with neurotoxic shellfish poisoning in humans (Baden et al., 1984). In the U.S., neurotoxic shellfish poisoning has been limited to the Gulf of Mexico and areas off the coast of Florida. The red tides are easily identified and are also associated with massive fish kills. Thus, the blooms of this toxic dinoflagellate are readily observed.

The mode of transmission of the toxins of *P. brevis* to humans is very similar to that discussed above for paralytic shellfish poisoning except that it occurs much more rarely. The filter-feeding molluscs feed on the toxic algae and retain the toxins in their edible tissues.

The symptoms of neurotoxic shellfish poisoning include tingling and numbness of the lips, tongue, throat, and area around the mouth; muscular aches; gastrointestinal complaints; and dizziness. Neurotoxic shellfish poisoning is seldom fatal. The onset time for this illness ranges from a few minutes to a few hours. The duration is also rather short, ranging from a few hours to a couple of days. There is no known antidote for neurotoxic shellfish poisoning.

P. brevis produces at least two neurotoxins called brevetoxins B and C (Baden et al., 1984). The brevetoxins are polyether-type compounds. They appear to bind to nerve cells, but their mechanism of action is unknown.

Monitoring for red tides should alert shellfish harvesters to the potential hazards associated with ingestion of shellfish from the affected areas. The typical fish kills will provide further evidence of the presence of this toxic dinoflagellate. Monitoring efforts should be focused on the Gulf of Mexico, since most red tides in the U.S. occur there.

Diarrhetic Shellfish Poisoning

Diarrhetic shellfish poisoning has been identified primarily in Japan, the Netherlands, and Chile (Kat, 1983; Yasumoto et al., 1984). Gastrointestinal complaints, including diarrhea, nausea, vomiting, and abdominal pain, predominate with this illness. Chills may also occur in a small percentage of the patients. The incubation period usually ranges from 30 min to several hours. The duration of the illness is rather short, although symptoms can continue for several days in severe cases. The causative shellfish in Japan have been mussels, scallops, and short-necked clams. The digestive organs of the shellfish seem to contain the majority of the toxins involved in diarrhetic shellfish poisoning. Cooking does not alter the toxins. A mouse bioassay exists for these toxins.

The causative dinoflagellates which produce the toxins involved in diarrhetic shellfish poisoning are *Dinophysis fortii* and *D. acuminata*. These dinoflagellates are widespread in occurrence, raising the possibility that this illness could affect other parts of the world under the appropriate conditions. The toxins produced by these dinoflagellates are polyether compounds. At least five related toxins are known

to exist: okadaic acid, two dinophysistoxins, and two pectenotoxins. The mechanism of action of these toxins is unknown, but their polyether structures suggest a mechanism similar to that of ciguatoxin and the brevetoxins, although neurological effects have not been observed in outbreaks.

Although these toxic dinoflagellates are widespread, the intoxication occurs chiefly when the digestive organs are consumed. Thus, one method of reducing the risk of diarrhetic shellfish poisoning would be to avoid ingesting the internal organs. The mouse bioassay could also be used to detect the presence of these toxins in the shellfish.

Further Research Needed

Seafoods represent an increasingly important and somewhat underutilized resource in the U.S. Marine microbial toxins can limit the consumption of certain types of seafood. Further research is needed to develop effective methods to prevent these illnesses. In particular, improved methods are needed for the detection of the ciguatera toxins. The factors controlling the blooms of the toxic dinoflagellates must be understood before effective methods can be developed to limit the occurrence and duration of these blooms. With regard to histamine poisoning, more research effort is needed to assess the importance of post-catching contamination as a possible source of the histamine-producing microorganisms.

References

AOAC. 1984. "Official Methods of Analysis of the Association of Official Analytical Chemists," 14th ed., ed. S. Williams, p. 344. Assn. Offic. Anal. Chem., Arlington, Va.

Anderson, D.M. 1984. Shellfish toxicity and dormant cysts in toxic dinoflagellate blooms. In Ragelis (1984a), p. 125.

Baden, D.G., Mende, T.J., Poli, M.A., and Block, R.E. 1984. Toxins from Florida's red tide dinoflagellate, *Ptychodiscus brevis*. In Ragelis (1984a), p. 359.

Bagnis, R., Chanteau, S., Chungue, E., Hurtel, J.M., Yasumoto, T., and Inoue, A. 1980. Origins of ciguatera fish poisoning: A new dinoflagellate, *Gambierdiscus toxicus* Adachi and Fukuyo, definitively involved as a causal agent. Toxicon 18: 199.

Bjeldanes, L.F., Schutz, D.E., and Morris, M.M. 1978. On the aetiology of scombroid poisoning: Cadaverine potentiation of histamine toxicity in the guinea pig. Food Cosmet. Toxicol. 16: 157.

Bond, R.M. and Medcof, J.C. 1957. Epidemic shellfish poisoning in New Brunswick. Can. Med. Assn. J. 79: 19.

Dickey, R.W., Miller, D.M., and Tindall, D.R. 1984. Extraction of a water-soluble toxin from a dinoflagellate, *Gambierdiscus toxicus*. In Ragelis (1984a), p. 257.

Hall, S. and Reichardt, P.B. 1984. Cryptic paralytic shellfish toxins. In Ragelis (1984a), p. 113.

Hokama, Y. and Miyahara, J.T. 1986. Ciguatera poisoning: Clinical and immunological aspects. J. Toxicol. Toxin Rev. 5: 25.

Hui, J.Y. and Taylor, S.L. 1985. Inhibition of *in vivo* histamine metaboliam in rats by foodborne and pharmacologic inhibitors of diamine oxidase, histamine N-methyltransferase, and monoamine oxidase. Toxicol. Appl. Pharmacol. 81: 241.

Jamieson, G.S. and Chandler, R.A. 1983. Paralytic shellfish poisoning in sea scallops *(Placopecten magellanicus)* in the west Atlantic. Can. J. Fish. Aquatic Sci. 40: 313.

Kat, M. 1983. *Dinophysis acuminata* blooms in the Dutch coastal area related to diarrhetic mussel poisoning in the Dutch Waddensea. Sarsia 68: 81.

Lawrence, D.N., Enriquez, M.B., Lumish, R.M., and Maceo, A. 1980. Ciguatera poisoning in Miami. J. Am. Med. Assn. 244: 254.

Legrand, A.M. and Bagnis, R. 1984. Mode of action of ciguatera toxins. In Ragelis (1984a), p. 217.

Lewis, N.D. 1984. Ciguatera in the Pacific: Incidence and implications for marine resource development. In Ragelis (1984a), p. 289.

Lyons, D.E., Beery, J.T., Lyons, S.A., and Taylor, S.L. 1983. Cadaverine and aminoguanidine potentiate the uptake of histamine *in vitro* in perfused intestinal segments of rat. Toxicol. Appl. Pharmacol. 70: 445.

McMillan, J.P., Granade, H.R., and Hoffman, P. 1980. Ciguatera fish poisoning in the United States Virgin Islands: Preliminary studies. J. Coll. Virgin Islands 6: 84.

Miller, D.M., Dickey, R.W., and Tindall, D.R. 1984. Lipid-extracted toxins from a dinoflagellate, *Gambierdiscus toxicus*. In Ragelis (1984a), p. 241.

Morris, J.G., Lewin, P., Hargrett, N.T., Smith, W., Blake, P.A., and Schneider, R. 1982. Clinical features of ciguatera fish poisoning: A study of the disease in the US Virgin Islands. Arch. Int. Med. 142: 1090.

Motil, K.J. and Scrimshaw, N.S. 1979. The role of exogenous histamine in scombroid poisoning. Toxicol. Lett. 3: 219.

Parrot, J.-L. and Nicot, G. 1966. Pharmacology of histamine. Absorption de l'histamine par l'appareil digestif. In "Handbook of Experimental Pharmacology," Vol. 18, Part 1, ed. M. Rocha e Silva, p. 148. Springer-Verlag, New York.

Ragelis, E.P. 1984a. "Seafood Toxins." Am. Chem. Soc., Washington, D.C.

Ragelis, E.P. 1984b. Ciguatera seafood poisoning: Overview. In Ragelis (1984a), p. 25.

Randall, J.E. 1980. A survey of ciguatera at Eniwetok and Bikini, Marshall Islands, with notes on the systematics and food habits of ciguatoxic fishes. Fish. Bull. 78: 201.

Ritchie, J.M. and Rogart, R.B. 1977. The binding of saxitoxin and tetrodotoxin to excitable tissue. Rev. Physiol. Biochem. Pharmacol. 79: 1.

Schantz, E.J. 1973. Seafood toxicants. In "Toxicants Occurring Naturally in Foods," 2nd ed., Comm. on Food Protection, p. 424. Natl. Acad. of Sciences, Washington, D.C.

Schantz, E.J. 1984. Historical perspective on paralytic shellfish poison. In Ragelis (1984a) p. 99.

Scheuer, P.J., Takahashi, W., Tsutsumi, J., and Yoshida, T. 1967. Ciguatoxin: Isolation and chemical nature. Science 155: 1267.

Taylor, F.J.R. 1984. Toxic dinoflagellates: Taxonomic and biogeographic aspects with emphasis on *Protogonyaulax*. In Ragelis (1984a), p. 77.

Taylor, S.L. 1985a. "Histamine Poisoning Associated with Fish, Cheese, and Other Foods." Monograph, World Health Org., Geneva.

Taylor, S.L. 1985b. Food allergies. Food Technol. 39(2): 98.

Taylor, S.L. 1986. Histamine food poisoning: Toxicology and clinical aspects. CRC Crit. Rev. Toxicol. 17: 91.

Taylor, S.L. 1987. Allergic and sensitivity reactions to food componenta. In "Nutritional Toxicology, Vol. II," ed. J.N. Hathcock, p. 173. Academic Press, Orlando, Fla.

Taylor, S.L. and Speckhard, M.W. 1983. Isolation of histamine-producing bacteria from frozen tuna. Mar. Fish. Rev. 45(4-6): 40.

Taylor, S.L., Hui, J.Y., and Lyons, D.E. 1984. Toxicology of scombroid poisoning. In Ragelis (1984a), p. 417.

Tindall, D.R., Dickey, R.W., Carlson, R.D., and Morey-Gaines, G. 1984. Ciguatoxic dinoflagellates from the Caribbean sea. In Ragelis (1984a), p. 225.

Yamani, M.I., Dickertmann, D., and Untermann, F. 1981. Histamine formation by *Proteus* species from tuna fish. Zbl. Bakt. Hyg., I Abt. Orig. B 173: 478.

Yasumoto, T., Nakajima, I., Bagnis, R., and Adachi, R. 1977. Finding of a dinoflagellate as a likely culprit of ciguatera. Bull. Japan. Soc. Sci. Fish. 43: 1021.

Yasumoto, T., Murata, M., Oshima, Y., Matsumoto, G.K., and Clardy, J. 1984. Diarrhetic shellfish poisoning. In Ragelis (1984a), p. 207.

Yentsch, C.M. 1984. Paralytic shellfish poisoning: An emerging perspective. In Ragelis (1984a), p. 9.

Based on a paper presented during the IFT Food Microbiology Division/Seafood Products Technology Group program, "Microbiology of Marine Food Products," at the Annual Meeting of the Institute of Food Technologists, Las Vegas, Nev., June 16–19, 1987.

—Edited by Neil H. Mermelstein, Senior Associate Editor

VIRAL DISEASE TRANSMISSION BY SEAFOODS

CHARLES P. GERBA

□ VIRAL DISEASE TRANSMISSION to humans via consumption of seafood was first recognized in the 1950s, when the first documented outbreaks of shellfish-associated hepatitis were reported (Roos, 1956; Lindberg-Braman, 1956). It was recognized over the intervening decades that shellfish could serve as an effective vehicle in the transmission of viral hepatitis and gastroenteritis.

The actual number of virus-associated outbreaks of gastroenteritis caused by shellfish consumption appears to be on the rise in the United States (Fig. 1). While no outbreaks of typhoid associated with shellfish consumption have occurred in the U.S. since 1955, outbreaks of virus-associated illness have continued to occur, suggesting that currently used bacterial indicators used to assess the sanitary quality of shellfish are not adequate to prevent viral disease by this route. Clearly, a better understanding of the ecology and epidemiology of human pathogenic viruses is needed, so that adequate measures can be developed for the control of disease transmission by shellfish.

Viruses Transmitted by Seafoods

Human enteric viruses appear to be the major cause of shellfish-associated viral disease. Presently, there are more than 100 known enteric viruses which are excreted in human feces and ultimately find their way into domestic sewage (Table 1). Enteric viruses are divided into several groups on the basis of morphologic, physical, chemical, and antigenic differences. These viruses cause a wide variety of illnesses, such as hepatitis, fever, diarrhea, paralysis, meningitis, myocarditis, etc. The list of known enteric viruses grew rapidly in the past two decades, as better methods became available for their detection.

Enteric viruses are those animal viruses which are believed to be principally transmitted by the fecal-oral route. They are excreted in large numbers in the feces of infected individuals and can almost always be detected in domestic sewage effluents. Enteric viruses are more resistant than enteric bacteria to common sewage treatment processes including chlorination as commonly practiced. They may enter the ocean through the direct discharge of domestic sewage into the marine environment or via sewage-contaminated rivers and streams. They may also gain entrance through the ocean disposal of domestic sewage sludge (Goyal, 1984) and from boat wastes.

The enteroviruses are small (28 nm), single-stranded RNA viruses, and they include members of the polio, echo, coxsackie, and hepatitis A (enterovirus type 72) groups. While many of the enterovirus infections such as those caused by poliovirus may be asymptomatic, symptomatic infections may be as high as 95% during outbreaks of hepatitis A virus (Lednar et al., 1985). In addition to hepatitis A (infectious hepatitis), epidemics of non-A, non-B hepatitis transmitted by the fecal-oral route have been documented (Wong et al., 1980). It is not serologically related to hepatitis A or B (serum hepatitis), and little is known about its exact nature, as it has yet to be grown in cell culture. This group may be represented by more than one type of virus.

The Norwalk virus and the Snow Mountain agent have been demonstrated to be the cause of both food- and waterborne disease outbreaks (Gerba et al., 1985; Brondum et al., 1985). These small viruses (27 nm) have not yet been grown in the laboratory, making basic characterization of them difficult. Astroviruses, caliciviruses, and several other Norwalk-like agents have been recognized as a cause of human gastroenteritis, but little is known about them.

Reo- and rotaviruses are large (70–80 nm), double-strand-

The author is Professor, Dept. of Nutrition and Food Science and Dept. of Microbiology and Immunology, University of Arizona, Tucson, AZ 85721

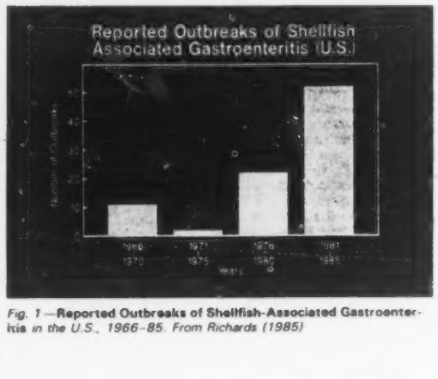


Fig. 1—**Reported Outbreaks of Shellfish-Associated Gastroenteritis** *in the U.S., 1966–85. From Richards (1985)*

Table 1—Enteric Viruses of Man

Virus	Disease caused
Poliovirus	Meningitis, paralysis, fever
Echovirus	Meningitis, diarrhea, rash, fever, respiratory disease
Coxsackievirus A	Meningitis, herpangina, fever, respiratory disease
Coxsackievirus B	Myocarditis, congenital heart anomalies, pleurodynia, respiratory disease, fever, rash, meningitis
New enteroviruses (Types 68–71)	Meningitis, encephalitis, acute hemorrhagic conjunctivitis, fever, respiratory disease
Hepatitis Type A (Enterovirus 72)	Infectious hepatitis
Norwalk virus	Diarrhea, vomiting, fever
Calicivirus	Gastroenteritis
Astrovirus	Gastroenteritis
Reovirus	Not clearly established
Rotavirus	Diarrhea, vomiting
Adenovirus	Respiratory disease, eye infections, gastroenteritis
Snow Mountain agent	Gastroenteritis
Epidemic non-A, non-B hepatitis	Hepatitis

ed RNA viruses. Rotaviruses are a significant cause of childhood gastroenteritis and are capable of causing severe diarrhea in adults. They have been documented as the cause of several waterborne disease outbreaks of gastroenteritis (Gerba et al., 1985).

Adenoviruses are large (80 nm), double-stranded DNA viruses that have been responsible for eye and respiratory infections among bathers. Recently, three new types of adenoviruses have been recognized as a cause of acute gastroenteritis in children (Uhnoo et al., 1984).

Epidemiology of Virus Transmission by Shellfish

Although there are more than 100 known enteric viruses, only a few have been shown epidemiologically to be transmitted by shellfish: hepatitis A, non-A, non-B hepatitis, Norwalk, Snow Mountain agent, astroviruses, caliciviruses, and small round viruses. Lack of methods for virus detection and the difficulty of recognizing viral disease outbreaks have probably precluded the list from being longer. It was not until the early 1960s that outbreaks of shellfish-associated infectious hepatitis were documented in the U.S. Since then, more than 1,000 cases of hepatitis A associated with shellfish consumption have been reported (Richards, 1985). Outbreaks are rather dramatic but still not easily detectable. More significant are the sporadic cases which are not evident as an outbreak.

Several epidemiological studies have suggested that shellfish may play a significant role in the transmission of hepatitis A virus (Fig. 2). In a recent case-controlled study, it was reported that 25% of the hepatitis A cases in southeast England could be attributed to the consumption of shellfish (O'Mahony et al., 1983). Stille et al. (1972) reported that consumption of contaminated molluscs accounted for an estimated 19% of the infectious hepatitis in Frankfurt, Germany. In the U.S., Koff et al. (1967) conducted a prospective study to determine the modes of transmission of nonepidemic infectious hepatitis cases among 10 Boston hospitals. Ingestion of raw shellfish was found to be significantly more frequent in infectious hepatitis patients (34/185) than in controls (10/185). Ingestion of steamed clams was more common in patients (13/104) than in matched controls; only 3 of the 13 patients had been exposed to jaundiced persons. When considered together, ingestion of steamed clams or raw shellfish was as frequent a potential exposure to hepatitis as was contact with jaundiced persons.

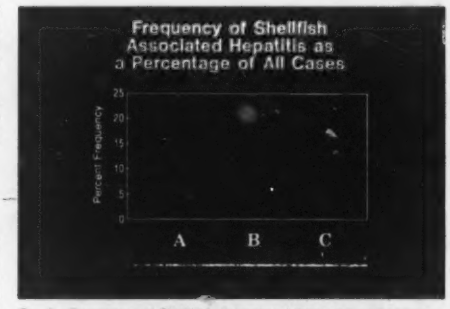


*Fig. 2—**Frequency of Shellfish-Associated Hepatitis** as a percentage of all cases, 1967-83. A = Koff et al. (1967); B = Stille et al. (1972); and C = O'Mahony et al. (1983), hepatitis A only*

Risk Factors Associated with Acquisition of Non A Non-B Hepatitis (Alter et al., 1982)
Raw Shellfish Consumption
Parenteral Drug Use
No Association
Blood Transfusions
Person Contact or Hospital Employment

*Fig. 3—**Risk Factors Associated** with acquisition of non-A, non-B hepatitis. Based on Alter et al. (1982)*

Three reports have implicated shellfish as a source of non-A, non-B hepatitis (Caredda et al., 1981; Alter et al., 1982; Bamber et al., 1983). In a study of patients in five Baltimore hospitals, Alter et al. (1982) founded that raw shellfish ingestion was associated with 12.5% of the cases of non-A, non-B hepatitis (Fig. 3). This was the third most common risk factor after parenteral drug use and history of blood transfusions. It is possible that different non-A, non-B hepatitis viruses were associated with the shellfish than with parenteral drug use and blood transfusion. Although hepatitis B virus (serum hepatitis) has been demonstrated in oysters near a hospital waste outfall (Mahoney et al., 1974), shellfish have never been shown to be a cause of infection.

The first documented outbreak of shellfish-associated Norwalk virus gastroenteritis involved more than 2,000 persons throughout Australia (Murphy et al., 1979). In the U.S., the first case of shellfish-associated gastroenteritis attributed to Norwalk virus, and documented as such, occurred in 1980, after individuals consumed oysters from Florida (Gunn et al., 1982). In 1980 in New York State, there were 103 well-documented outbreaks in which more than 1,000 persons became ill with diarrhea from eating clams and oysters. Norwalk virus was identified in both clam and oyster specimens, as well as serologically in five of seven of the outbreaks. Importation of depurated English clams led to yet another round of enteric virus illness (Richards, 1985). A review by Guzewich and Morse (1986) indicates that Norwalk virus illness associated with shellfish is a continuing problem in the U.S.

A group of small round viruses have been reported as the cause of numerous outbreaks of shellfish-associated gastroenteritis (Appleton and Pereira, 1977; Gill et al., 1983). These viruses do not appear to be serologically related to the Norwalk virus. More recently, the Snow Mountain agent, astroviruses, and caliciviruses have been reported as the cause of several shellfish-associated outbreaks of gastroenteritis (Dolin et al., 1987; Kurtz and Lee, 1987).

In addition to hepatitis and gastroenteritis, two epidemiological studies have also suggested a possible link between Creutzfeldt-Jakob disease and consumption of raw shellfish. However, these studies were of a limited scope, and the link has not been conclusively established (Bobowick et al., 1973; Davanipour et al., 1985).

Survival of Enteric Viruses

Numerous studies have been conducted on the survival of viruses in marine waters. Although the survival of enteric viruses in marine waters appears to be lower than that observed in freshwater environments, they are still capable of prolonged survival in this environment. In laboratory studies, enteric viruses have been reported to survive from 2 to 130 days in seawater, and they generally survive longer in such environments than do coliform bacteria (Melnick and Gerba, 1980). However, Goyal et al. (1984) was able to isolate enteroviruses from sediment and blue crabs at the Philadelphia dump site 18 mo after sludge disposal had stopped. Almost all previous studies on virus survival have concerned enteroviruses and coliphages. However, studies with hepatitis A virus (Boach and Shields, 1987) suggest that they are capable of longer survival than other enteric viruses (Fig. 4).

A number of variables have been found to affect virus survival. These include temperature, salinity, microbial antagonism, solar radiation, and association of viruses with solids (Kapuscinski and Mitchell, 1980). Of the many factors which can influence virus survival, temperature is the most important. At temperatures below 10°C, enteric viruses could be expected to survive for several months. Marine sediments also act to protect viruses against inactivation, perhaps by reducing the rate of thermoinactivation (Liew and Gerba, 1980). Generally, when sediment was present, inactivation rates of viruses in seawater-moistened sand tended to be 4.5 times slower than in seawater alone (Gerba and Goyal, 1986). This probably explains why Goyal (1984) was able to detect enteric viruses in marine sediments at the Philadelphia sludge dumpsite 18 mo after disposal had stopped.

Occurrence in Fish and Shellfish

Fish, shellfish, and crabs that live in water contaminated by domestic wastes are frequently found to contain enteric bacteria and viruses. In addition, laboratory studies have demonstrated that lobsters, sandworms, detrital feeding fish, conch, and aplysia can accumulate enteric viruses (Sigel et al., 1976; Gerba and Goyal, 1978; Metcalf, 1976). However, only shellfish have been implicated in the transmission of enteric viral illness, probably because they are not as thoroughly cooked as other seafoods or are eaten raw. In addition, shellfish, as filter feeders, tend to concentrate viruses from the water in which they are growing. Bivalve molluscs sieve out suspended food particles from a current of water passing through the shell cavity. Shellfish thus act to concentrate viruses from the water in which they live, and viruses may occur in the shellfish at concentrations much higher than in the overlaying water.

The occurrence of enteroviruses in shellfish taken from the coastal waters of the U.S. has been documented in numerous studies (Gerba and Goyal, 1978; Goyal et al., 1979; Vaughn et al., 1980; Ellender et al., 1980; Wait et al., 1983). In all of these studies, enteroviruses were isolated from areas open to shellfish harvesting. The range of concentration of enteroviruses isolated from shellfish in these studies is shown in Figure 5. In these studies, the percentage of virus-positive shellfish ranged from 9 to 40% for open waters vs 13 to 40% for closed waters. No statistically significant relationship has been shown between concentrations of enteric viruses and coliform or fecal coliforn bacteria in shellfish or shellfish growing waters (Goyal et al., 1979; Wait et al., 1983).

While a variety of marine animals have been shown to be capable of accumulating enteric viruses when placed in virus-contaminated marine waters, field studies have only demonstrated the presence of enteric viruses in one marine organism other than shellfish: Goyal (1984) reported the isolation of enteroviruses from blue crabs from the Philadelphia sludge dump site in the North Atlantic.

Depuration and Relaying

Depuration and relaying are methods which are used for the self-purification of contaminated shellfish. They rely on the ability of the shellfish to eliminate contaminating microorganisms from the digestive tract through normal feeding, digestion, and excretion activities. Artificial purification or depuration of shellfish takes place in tanks or basins which are filled with disinfected water under stable environmental conditions (temperature and salinity). When shellfish are relayed, they are moved to areas in the natural environment which are unpolluted.

Depuration of shellfish for commercial purposes is expensive and is practiced only on a limited scale in the U.S. (Cook and Ellender, 1986). Relaying currently is a much more common practice. Maximum depuration is possible only when environmental conditions such as temperature and salinity are optimized. The concentrations of enteroviruses are rapidly reduced under optimal conditions during both relaying and depuration. However, while fecal indicator bacteria and enteric bacterial pathogens are eliminated at similar rates, fecal coliform levels apparently do not correlate with virus elimination (Cook and Ellender, 1986). Recent research also suggests that hepatitis A virus may not be eliminated as readily as other enteroviruses during depuration (Sobsey, 1987) and may help explain the association of shellfish-associated viral outbreaks with depurated shellfish (Grohmann et al., 1981; Richards, 1985). It appears, therefore, that fecal coliforms are not useful as end-point indicators of depuration or relaying. However, depuration of shellfish, if properly conducted, will reduce the risk, but the product cannot be guaranteed to be virus free (Metcalf et al., 1980).

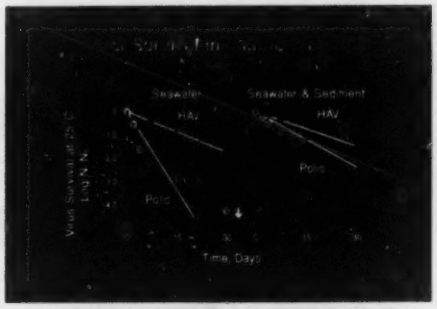


Fig. 4—**Viral Survival in Marine Waters.** *From Bosch and Shields (1987). N_o = initial virus concentration; N = virus concentration at time indicated; HAV = hepatitis A virus; and polio = poliovirus type 1*

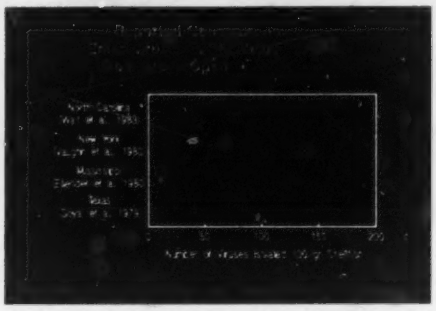


Fig. 5—**Range of Reported Concentrations of Enteroviruses** *in shellfish collected from areas open to harvesting*

Uptake of enteric viruses by shellfish or other marine animals may act to prolong their survival (Hedstrom and Lyke, 1964). No multiplication of human enteric viruses in shellfish has been demonstrated. Enteric viruses may survive for weeks or months in refrigerated marine foods (Gerba and Goyal, 1978). In one outbreak of gastroenteritis caused by the Norwalk virus, the shellfish had been frozen for 15 weeks before consumption (Linco and Grohman, 1980). Poliovirus has been reported to survive 30–90 days in refrigerated oysters (DiGirolamo et al., 1970). Poliovirus has been found to survive up to 300 days on peeled prawns at −20°C (Eyles, 1983), and prolonged survival of virus in crabs has also been reported (DiGirolamo and Daley, 1973). Steamed and undercooked shellfish have been implicated in outbreaks of Norwalk virus and hepatitis A virus (Feingold, 1973; Morse et al., 1986). Opening the shells of soft-shelled clams 1 min after steaming is not sufficient to kill all contaminating viruses (Koff and Sear, 1967).

DiGirolamo et al. (1970) reported that 7–13% of added poliovirus survived in oysters even after processing by four commonly used methods, namely, steaming, frying, baking,

and stewing. Heat penetration studies showed that the internal temperature was not sufficient to inactivate all virus present. In animal feeding studies, hepatitis A virus failed to be totally inactivated after thermal treatment of oysters at 140°F for 19 min (Peterson et al., 1978). Boiling for at least 20 min has been advocated (Mosley and Galambos, 1975).

Poliovirus 1 in oysters is able to survive relatively high doses of gamma radiation (DiGirolamo et al., 1972). To inactivate more than 90% of the virus present required a dose of 400 krad, which resulted in undesirable organoleptic changes.

Methods for Virus Detection in Shellfish

Various methods have been developed for the recovery of enteric viruses from shellfish and other seafoods (Sobsey, 1985). All of these methods begin with the homogenization of the whole or shucked shellfish or part of it. In earlier methods, this homogenate, with or without addition of diluent, was centrifuged to remove solids. The supernatant fluid was then assayed—directly or after further clarification by treatment with a lipid solvent—in animal cell culture. However, the presence of cytoturic components in some shellfish and the large volume of homogenate which had to be assayed to detect low levels of virus led to the development of methods for the concentration of viruses from the shellfish tissue. These methods generally involve the adsorption of viruses to the shellfish meat, followed by elution and then concentration to a small volume by flocculation, hydroextraction, or ultrafiltration.

Enteric viruses are detected by assay on animal cell culture, which may require a few days to several weeks. Most studies on enteric viruses in shellfish have been limited to enteroviruses because of their ease of detection in cell culture. Cell culture techniques have recently become available for the growth and detection of hepatitis A virus (Provost and Hilleman, 1979). However, cost and time for assay seriously limit monitoring efforts for enteric viruses in shellfish and their growing waters. Margolin et al. (1986) described the development of gene probes capable of detecting one infectious unit of poliovirus or hepatitis A virus in environmental samples in 48–72 hr. They have also been able to detect one plaque forming unit of poliovirus type 1 in concentrations of shellfish homogenates (Margolin et al., 1987) also using gene probes. The use of gene probes significantly reduces the cost and time for assay and may allow for more routine monitoring for enteric viruses in shellfish in the future.

References

Alter, M.J., Gerety, R.J., Smallwood, L.A., Sampliner, R.E., Tabor, E., Deinhardt, F., Frosner, G., and Matanoski, G.M. 1982. Sporadic non-A, non-B hepatitis: Frequency and epidemiology in an urban U.S. population. J. Infect. Dis. 145: 886.

Appleton, H. and Pereira, M.S. 1977. A possible virus aetiology in outbreaks of food-poisoning from cockles. Lancet ii: 780.

Bamber, M., Thomas, H.C., Bannister, B., and Sherlock, S., 1983. Acute type A, B, and non-A, non-B hepatitis in a hospital population in London: Clinical and epidemiological features. Gut 24: 561.

Bobowick, A.R., Brody, J.A., Matthews, M.R., Roos, R., and Gajdusek, D.C., 1973. Creutzfeldt-Jakob disease: A case-control study. Am. J. Epidemiol. 98: 381.

Bosch, A. and Shields, P.A. 1987. Survival of hepatitis A virus and poliovirus in seawater and marine sediments. Abstr. Ann. Mtg. Am. Soc. Microbiol., p. 295.

Brondum, J., Spitalny, K.C., Vogt, R.L., Godlewski, K., Madore, H.P., and Dolin, R. 1985. Snow Mountain agent associated with an outbreak of gastroenteritis in Vermont. J. Infect. Dis. 152: 834.

Caredda, F., D'Aminio Monforte, A., Rossi, E., Lopez, S., and Moroni, M. 1981. Non-A, non-B hepatitis in Milan. Lancet ii: 48.

Caredda, F., Antinori, S., Re, T., Pastecchia, C., and Moroni, M. 1986. Acute non-A non-B hepatitis after typhoid fever. Brit. Med. J. 292: 1429.

Cook, D.W. and Ellender, R.D. 1986. Relaying to decrease the concentration of oyster-associated pathogens. J. Food Protect. 49: 116.

Cubitt, W. D. 1987. The candidate caliciviruses. In "Novel Diarrhoea Viruses," p. 92. John Wiley and Sons, Chichester, U.K.

Dolin, R., Treanor, J.J., and Madore, P. 1987. Novel agents of viral gastroenteritis. J. Infect. Dis. 155: 365.

Davanipour, Z., Alter, M., Sobel, E., Asher, O.M., and Gajdusek, D.C. 1985. A case-control study of Creutzfeldt-Jakob disease. 122: 443.

DiGirolamo, R. and Daley, M. 1973. Recovery of bacteriophage from contaminated, chilled and frozen samples of edible West Coast crabs. Appl. Microbiol. 25: 1020.

DiGirolamo, R., Liston, J., and Matches, J.R. 1970. Survival of virus in chilled, frozen and processed oysters. Appl. Microbiol. 20: 58.

DiGirolamo, R.J., Liston, J., and Matches, J. 1972. Effects of irradiation on the survival of virus in West Coast oyster. Appl. Microbiol. 24: 1005.

Ellender, R.D., Mapp, J.B., Middlebrooks, B.L., Cook, D.W., and Cake, E.W. 1980. Natural enterovirus and fecal coliform contamination of Gulf Coast oysters. J. Food Protect. 43: 105.

Eyles, M.J. 1983. Assessment of cooked prawns as a vehicle for transmission of viral disease. J. Food Protect. 46: 426.

Feingold, A. 1973. Hepatitis from eating steamed clams. J. Am. Med. Assn. 225: 527.

Gerba, C.P. and Goyal, S.M. 1978. Detection and occurrence of enteric viruses in shellfish: A review. J. Food Protect. 41: 743.

Gerba, C.P. and Goyal, S.M. 1986. Development of a qualitative pathogen risk assessment methodology for ocean disposal of municipal sludge. EC 140-CIN-493. Environmental Protection Agency. Cincinnati, Ohio.

Gerba, C.P., Singh, S.N., and Rose, J.B. 1985. Waterborne viral gastroenteritis and hepatitis. CRC Crit. Rev. Environ. Control 15: 213.

Gill, O.N., Cubitt, W.D., McSwiggan, O.A., Watney, B.M., and Bartlett, C.L.R. 1983. Epidemic of gastroenteritis caused by oysters contaminated with small round structured viruses. Brit. Med. J. 287: 1532.

Goyal, S.M. 1984. Viral pollution of the marine environment. CRC Crit. Rev. Environ. Control 14: 1.

Goyal, S.M., Gerba, C.P., and Melnick, J.L. 1979. Human enteroviruses in oysters and their overlaying waters. Appl. Environ. Microbiol. 37: 572.

Goyal, S.M., Adams, W.N., O'Malley, M.L., and Lear, D.W. 1984. Human pathogenic viruses at sewage sludge disposal sites in the middle Atlantic region. Appl. Environ. Microbiol. 48: 758.

Grohmann, G.S., Murphy, A.M., Christopher, P.J., Auty, G., and Greenberg, H.B. 1981. Norwalk virus gastroenteritis in volunteers consuming depurated oysters. Australian J. Exp. Biol. Med. Sci. 59: 219.

Gunn, R.A., Janowski, H.T., Lieb, S., Prather, E.C., and Greenberg, H. 1982. Norwalk virus gastroenteritis following raw oyster consumption. Am. J. Epidemiol. 115: 348.

Guzewich, J.J. and Morse, D.L. 1986. Sources of shellfish in outbreaks of probable viral gastroenteritis: Implications for control. J. Food Protect. 49: 389.

Hestrom, C.E. and Lyke, E. 1964. An experimental study on oysters as virus carriers. Am. J. Hyg. 79: 134.

Kapuscinski, R.B. and Mitchell, R.B. 1980. Processes controlling virus inactivation in coastal waters. Water Res. 14: 363.

Koff, R.S. and Sear, H.S. 1967. Internal temperature of steamed clams. New Eng. J. Med. 276: 737.

Koff, R.S., Grady, G.F., Chalmers, T.C., Mosley, J.W., and Swartz, B.L. 1967. Viral hepatitis in a group of Boston hospitals. III. Importance of exposure to shellfish in a non-epidemic period. New Eng. J. Med. 276: 703.

Kurtz, J.B. and Lee, T.W. 1987. Astroviruses: Human and animal. In "Novel Diarrhoea Viruses," p. 92. John Wiley & Sons, Chichester, U.K.

Lednar, W.M., Lemon, S.M., Kirkpatrick, J.W., Redfield, R.R., Fields, M.L., and Kelley, P.W. 1985. Frequency of illness associated with epidemic hepatitis A virus infections in adults. Am. J. Epidemiol. 122: 226.

Liew, P. and Gerba, C.P. 1980. Thermostabilization of enteroviruses by estaurine sediment. Appl. Environ. Microbiol. 40: 305.

Linco, S.J. and Grohmann, G.S. 1980. The Darwin outbreak of oyster-associated viral gastroenteritis. Med. J. Australia 1: 211.

Lindberg- Braman, A.M. 1956. Clinical observations on the so-called oyster hepatitis. Am. J. Publ. Health 53: 1003.

Mahoney, P., Fleischner, G., Millman, I., London, W.T., Blumberg, B.S., and Arias, I.M. 1974. Australia antigen: Detection and transmission in shellfish. Science 183: 80.

Margolin, A.B., Hewlett, M.J., and Gerba, C.P. 1986. Use of a cDNA dot-blot hybridization technique for detection of enteroviruses in water. In Proc. of Water Quality Technology Conf., Am. Water Works Assn., Denver, Colo., p. 87.

Margolin, A.B., Bitrick, M.S., and Gerba, C.P. 1987. Unpublished results. Univ. of Arizona, Tucson.

Melnick, J.L. and Gerba, C.P. 1980. The ecology of enteroviruses in natural waters. CRC Crit. Rev. Environ. Control 10: 65.

Metcalf, T.G. 1976. Prospects for virus infections in man and animals from domestic waste land disposal practices. In "Virus. Aspects of Applying Municipal Waste to Land," ed. L.B. Baldwin, J.M. Davidson, and J.S. Gerber, p. 97. Univ. of Florida, Gainesville.

Metcalf, T.G., Eckerson, D., Moulton, E., and Larkin, E.P. 1980. Uptake and depletion of particulate-associated polioviruses by the soft shell clam. J. Food Protect. 43: 87.

Mosley, J.W. and Galambos, J.T. 1975. Viral Hepatitis. In "Diseases of the liver," 4th ed., ed. L. Schiff, p. 500. J.B. Lippincott, Philadelphia, Pa.

Morse, D.L., Guzewich, J.J., Hanrahan, J.P., Stricof, R., Shayegani, M., Deibel, R., Grabau, J.C., Nowak, N.A., Herrmann, J.E., Cukor, G., and Blacklow, N.R. 1986. Widespread outbreaks of clam- and oyster-associated gastroenteritis. New Eng. J. Med. 314: 678.

Murphy, A.M., Grohmann, G.S., Christopher, P.J., Lopez, W.A., Davey, G.R., and Millsom, R.H. 1979. An Australia-wide outbreak of gastroenteritis from oysters caused by Norwalk virus. Med. J. Australia 2: 329.

O'Mahony, M.C., Gooch, C.D., Smyth, D.A., Thrussel, A.J., Bartlett, C.L.R., and Noah, N.D. 1983. Epidemic hepatitis A from cockles. Lancet i: 518.

Peterson, D.A., Wolfe, L.G., Larkin, E.P., and Deinhardt, F.W. 1978. Thermal treatment and infectivity of hepatitis A virus in human feces. J. Med. Virology 2: 201.

Provost, P.J. and Hilleman, M.R. 1979. Propagation of human hepatitis A virus in cell culture in vitro. Proc. Soc. Exp. Biol. Med. 160: 213.

Richards, G.P. 1985. Outbreaks of shellfish-associated enteric virus illness in the United States: Requisite for development of viral guidelines. J. Food Protect. 48: 815.

Roos, R. 1956. Hepatitis epidemic conveyed by oysters. Svenska Lakartidningen 53: 989.

Sigel, M.M., Rippe, D.F., Beasley, A.R. and Dorsey, M. 1976. Systems for detecting viruses and viral activity. In "Viruses in Water," ed. G. Berg, H.L. Bodily, E.H. Lennette, J.L. Melnick, and T.G. Metcalf, p. 139. Am. Pub. Health Assn., Washington, D.C.

Sobsey, M.D. 1985. Procedures for the virological examination of seawter, shellfish, and sediment. In "Laboratory Procedures for the Examination of Seawater and Shellfish," 5th ed., ed. A.E. Greenberg and D.A. Hunt, p. 81. Am. Pub. Health Assn., Washington, D.C.

Sobsey, M.D. 1987. Personal communication. Univ. of North Carolina, Chapel Hill.

Stille, W., Kunkel, B., and Nerger, K. 1972. Oyster-transmitted hepatitis. Dtsch. Med. Wschr. 97: 145.

Uhnoo, I., Wadell, G., Svensson, L., and Johannson, M.E. 1984. Importance of enteric adenoviruses 40 and 41 in acute gastroenteritis in infants and young children. J. Clin. Microbiol. 20: 365.

Vaughn, J.M., Landry, E.F., Thomas, M.Z., Vicale, T.J., and Panello, W.F. 1980. Isolation of naturally occurring enteroviruses from a variety of shellfish species residing in Long Island and New Jersey marine embayments. J. Food Protect. 43: 95.

Wait, D.A., Hackney, C.R., Carrick, R.J., Lovelack, G., and Sobsey, M.D. 1983. Enteric bacterial and viral pathogens and indicator bacteria in hard shell clams. J. Food Protect. 46: 493.

Wong, D.C., Purcell, R.H., Sreenivasan, M.A., Prasad, S.R., and Pavri, K.M. 1980. Epidemic and endemic hepatitis in India: Evidence for a non-A, non-B hepatitis virus aetiology. Lancet ii: 876.

Based on a paper presented during the IFT Food Microbiology Division/Seafood Products Technology Group program, "Microbiology of Marine Food Products," at the Annual Meeting of the Institute of Food Technologists, Las Vegas, Nev., June 16–19, 1987.

—Edited by Neil H. Mermelstein, Senior Associate Editor

SEAFOOD-BORNE BACTERIAL PATHOGENS OF MARINE ORIGIN

CAMERON R. HACKNEY AND ANGELA DICHARRY

□ SEAFOOD-BORNE DISEASES are frequently divided into three categories based on the major source of the responsible agent: agents naturally present in the environment; agents derived from pollution of the aquatic environment; and agents from workers and processing and foodservice environments. This review will focus on seafood-borne pathogens of marine origin; specifically members of the family *Vibrioaceae* and *Clostridium botulinum* type E.

Vibrios Associated with Foodborne Illness

Historically, *Vibrio cholerae* O1 has been the *Vibrio* of most concern with respect to public health; all other species and serotypes were referred to as nonagglutinable or noncholera vibrios (Blake, 1980; Desmarchelier, 1984). However, *Vibrio* is a large genus, containing 28 species plus numerous biotypes and chemovars (Oliver, 1985). At least 11 species are recognized as pathogenic or potentially pathogenic to humans.

Vibrios may cause a variety of diseases (Table 1), including gastroenteritis, wound infection, ear infection, and primary and secondary septicemia (Morris and Black, 1985). Of the 11 species pathogenic for humans, only six are associated with foodborne disease: *V. cholerae*, *V. parahaemolyticus*, *V. vulnificus*, *V. mimicus*, *V. hollisae*, and perhaps *V. furnissii*.

• **O1 *V. cholerae*.** *V. cholerae* is usually divided into two groups, serotype O1 and non-O1. Those groups can be further subdivided as toxigenic and nontoxigenic. Toxigenic strains are capable of producing cholera toxin or a very similar toxin.

V. cholerae O1 is the causative agent of endemic or Asiatic cholera. The O1 serotype contains two biotypes—classical and El Tor—both of which may contain toxigenic and nontoxigenic strains. The biotypes are differentiated by sensitivity to polymyxin B and Murkee's group 4 phage and by the ability to agglutinate chicken red blood cells (Sakazaki, 1979). The classical biotype predominated worldwide until the 1960s. The El Tor biotype is currently predominant worldwide and is the biotype associated with recent cases in the United States (Blake et al., 1980; Levine, 1981; Morris and Black, 1985; CDC, 1986a; b).

Symptoms of *V. cholerae* O1 infection can range from none to mild diarrhea to severe illness (cholera gravis). In severe cases, *V. cholerae* O1 can cause profuse watery diarrhea, dehydration, and death if not promptly treated. The incubation period varies from 6 hr to 5 days. Initially, the stool is brown with fecal material, but it quickly assumes the classic "rice-water" appearance. Enormous amounts of fluids are passed effortlessly, and the victim may lose 1 liter or more of fluid/hr, resulting in dehydration and circulatory collapse. The stool is rich in potassium and bicarbonate. Renal function is suppressed, and the patient suffers from severe thirst, leg cramps, hoarse speech, weakness, and rapid pulse (Morris and Black, 1985; Blake et al., 1980; Sakazaki, 1979).

Fortunately, cholera gravis is relatively uncommon. It results in only 1 in 25–100 infections by the El Tor biotype and in 1 in 5–10 infections by the classical biotype. People with type O blood are more susceptible to the severe disease (Sakazaki, 1979).

The infective dose for *V. cholerae* is estimated to be approximately 1 billion cells; however, consumption of antacids or medication to lower gastric acidity markedly lowers the infective dose (Blake, 1987). *V. cholerae* O1 induces illness by elaborating cholera toxin, which stimulates the production of cyclic AMP (Holmgien, 1981). Therefore only toxigenic strains can cause cholera. Nontoxigenic strains can cause diarrhea but not cholera; they have also been implicated in wound infections.

Cholera in the U.S. is relatively rare. The U.S. had been spared any identified cholera outbreak from 1911 until 1973, when a single unexplained case occurred in Texas. A second cholera outbreak occurred during August, September, and October 1978, when 11 people were infected with *V. cholerae* O1 El Tor from recontaminated cooked crabs (Blake et al., 1980). In 1981 there were two cases of cholera involving residents of the Texas Gulf Coast and 17 additional cases on an oil rig in the Gulf (Morris and Black, 1985). Thirteen cases of domestically acquired cholera occurred in 1986—12 in Louisiana and one in Florida (CDC, 1986b). Inadequate cooking or improper handling of crustaceans seems to have been the vehicle in these outbreaks. Ten of the patients had severe diarrhea, and 7 required hospitalization. The *V. cholerae* O1 was of the El Tor biotype.

Cholera was once thought to be mostly a water-borne disease, but in recent years the transmission of *V. cholerae* by food has been well established (Kolvin and Roberts, 1982). Outbreaks of cholera have occurred in several countries, where food was the vehicle of transmission. Foods involved include raw or partially cooked molluscs, other raw seafood, recontaminated cooked crabs, and even raw vegetables. *V. cholerae* O1 has a relatively short generation time and can grow quickly if foods are temperature abused.

V. cholerae O1 is widely distributed and is probably part of the indigenous bacterial flora in estuarine waters (Speck, 1985; Colwell, 1984). There is evidence of seasonal variation, and most cases of domestically acquired cholera have occurred during the late summer and fall, with August being the month for infection (Madden et al., 1982).

Current methodology for the isolation of *V. cholerae* from the environment may not adequately recover all viable cells. Research at the University of Maryland has demonstrated that *V. cholerae* may undergo a nonrecoverable stage that is probably associated with nutrient depletion. The researchers have combined the methods of immunofluorescent microscopy, acridine orange direct counting, and direct viable counts. Using these methods, they were able to detect viable cells that could not be detected by normal isolation procedures. The cells can revert to recoverable cells when special procedures are used. This research may explain why outbreaks of cholera may occur in areas where *V. cholerae* could not be previously recovered from the environment (Colwell et al., 1985; Xu et al., 1982).

• **Non-O1 *V. cholerae*.** At least 70 other groups of *V. cholerae* are known to exist. They are referred to collectively as non-O1 *V. cholerae* or nonagglutinable (NAG) *V. cholerae*. The majority of the strains isolated from seafood and patients are nontoxigenic strains; fewer than 5% of the non-O1 strains from human sources in the U.S. produce cholera toxin. The nontoxigenic strains are principally asso-

Author Hackney is Associate Professor and Superintendent, Seafood Agricultural Experiment Station, Virginia Polytechnic Institute & State University, P.O. Box 369, Hampton, VA 23669. Author Dicharry is Seafood Technologist, Gulf Coast Research Laboratory, J.L. Scott Marine Education Center, 1650 E. Beach Blvd., Biloxi, MS 39530. Send reprint requests to author Hackney

Table 1—**Diseases Associated with *Vibrio* Species**

Species	Disease[a]					Reference
	Gastroenteritis	Wound infection	Ear infection	Septicemia: Primary	Septicemia: Secondary	
V. alginolyticus		•	•		•	Morris and Black (1985)
V. cholerae						Morris and Black (1985), Blake et al. (1980)
O1 toxigenic +	•					
O1 toxigenic −	•					
non-O1 toxigenic +	•					
non-O1 toxigenic −	•	•	•	(•)	(•)	
V. cincinnatiensis				•		Bode et al. (1986)
V. damsela		•				Coffey et al. (1986)
V. fluvialis	•					Morris and Black (1985)
V. furnissii	•					Brenner et al. (1983)
V. hollisae	•					Morris et al. (1982)
V. metschnikovii	?			?		Blake (1980)
V. mimicus						Blake (1980)
Toxigenic +	•					
Toxigenic −	•		•			
V. parahaemolyticus	•	•	(•)		(•)	Sakazaki (1979)
V. vulnificus	(•)	•		•	•	Oliver (1985)

[a] • = most common clinical presentation; • = other clinical presentations; (•) = very rare presentation; and ? = suspected but not proven

ciated with gastrointestinal illness; but in the U.S. about one-third of the human isolates are from extraintestinal sources, including wound infections, ear infections, and primary and secondary septicemia (Morris and Black, 1985). Associated symptoms of gastroenteritis have included diarrhea (100% of the cases, 25% with bloody stools), abdominal cramps (93%), and fever (71%). Nausea and vomiting occur in 21% of the victims. The diarrhea may occasionally be severe, with as many as 20–30 watery stools/day (Morris and Black, 1985).

Almost all of the cases of non-O1 *V. cholerae* infections in the U.S. have been associated with eating raw oysters; but egg and asparagus salad and potatoes have also been vehicles for the bacteria.

Considering the relative frequency of isolation from seafood, the reported incidence of illness is very low. There is evidence that victims often have an underlying liver disease, which might be a host factor for the disease. Also, in most cases the disease may not be severe enough to warrant medical attention and therefore the incidence may be underreported.

Non-O1 *V. cholerae* strains are widely distributed in the environment. They occur most frequently in bays and estuaries with salinity in the area of 0.4–1.7% (Colwell and Kaper, 1978); but they have also been found in rivers and brackish inland lakes with salinity levels as low as 0.01%. Their presence in oysters and water samples does show a seasonal variation, with the highest numbers being isolated in June–August (Madden et al., 1982). Non-O1 *V. cholerae* are free-living organisms and are part of the autochthonous flora.

● ***V. parahaemolyticus.*** This species was first associated with food poisoning in 1950 in Osaka, Japan (Fujino et al., 1974). Since its discovery, it has been implicated in more than 1,000 outbreaks/year in Japan, and it accounts for 45–70% of that country's bacterial food poisonings. Food poisoning in Japan is usually related to the consumption of raw seafood during the warm months. Typical symptoms include diarrhea (sometimes bloody), abdominal cramps, nausea, vomiting, headaches, fever, and chills (Fujino et al., 1974). The infective dose for humans is between 10^5 and 10^7 viable cells; however, a decrease in stomach acidity may decrease the infective dose. The time for onset of symptoms is usually 9–25 hr, and the duration of the illness is usually 2.5–3 days. No deaths have been reported in the U.S., but a death rate of 0.04% is reported for Japan. In Japan, raw seafood is the usual vehicle for the organism; but in the U.S., most of the foods implicated in *V. parahaemolyticus* outbreaks are cooked seafoods that have been recontaminated, although raw oysters and raw crabs have been implicated in some outbreaks (Barker, 1974; Blake, 1980; Spite et al., 1978).

V. parahaemolyticus is widely distributed in nature and has been isolated from coastal waters worldwide. Its presence has been documented in virtually all the marine coastal environs of the U.S., from the coast of Maine south to the Gulf of Mexico, all along the West Coast, and in the coastal waters of Hawaii (Fujino, 1974; Blake, 1980). It is not considered to be a microorganism of the open sea because it cannot withstand the cool temperatures and high hydrostatic pressure (Kaneko and Colwell, 1978; Colwell, 1984; Schwarz and Colwell, 1974). Its presence in estuarine environments and in the seafood harvested from these environments usually shows a seasonal variation, being present in the highest numbers during the summer months (Kaneko and Colwell, 1978; Hackney et al., 1980). Thompson and Vanderzant (1976a) did not observe a positive correlation between numbers and season in the Gulf of Mexico off the Texas coast. However, Paille et al. (1987) observed seasonal variation in numbers of *V. parahaemolyticus* in oysters and waters of Louisiana.

While *V. parahaemolyticus* is a common contaminant of seafood, often present in high numbers, almost none of the isolates from seafood are capable of causing gastroenteritis in man (Fujino et al., 1974; Blake, 1980; Hackney et al., 1981). The test most widely used to differentiate between virulent and avirulent strains is the Kanagawa reaction, which tests a strain's ability to produce a heat-stable hemolysin in an agar medium containing 7% NaCl, mannitol, and fresh human or rabbit red blood cells. The heat-stable hemolysin is the main virulence determinant for *V. parahaemolyticus*. Isolates from the marine environment and seafood are predominantly Kanagawa negative. Thompson and Vanderzant (1976b) reported that only 0.18% of the isolates from water, shellfish, and sediments of the Gulf of Mexico were Kanagawa positive.

—*Continued on next page*

In Japan, 99% of the sea and fish isolates are Kanagawa negative (Sakazaki, 1979).

Food poisoning victims usually only excrete Kanagawa-positive isolates. Studies have demonstrated that isolates do not change in the intestinal tract and that Kanagawa-positive types are probably part of marine *V. parahaemolyticus* populations but are present in low numbers. Current methodology often fails to recover a large portion of the total population (Ray et al., 1978; Beuchat, 1977). Also, the methodology is needed to selectively isolate Kanagawa-positive isolates. Studies in our laboratory have indicated that enrichment in glucose salt teepol broth, as is currently recommended, actually favors the growth of Kanagawa-negative strains. On the other hand, media which do not contain surface-active agents such as teepol do not favor Kanagawa-negative strains. In laboratory studies, Dicharry (1983) observed that 150 μg of Streptomycin/mL in tryptic case soy broth containing 1% mannitol favored the growth of Kanagawa-positive isolates. She was able to selectively isolate Kanagawa-positive strains from laboratory cultures having a ratio of >1,000 Kanagawa-negative cells to 1 Kanagawa-positive cell. However, no Kanagawa-positive strains were isolated in later field tests.

● ***V. vulnificus.*** This species has been called the new "terror of the deep" and is one of the most invasive species ever described (Oliver, 1985). It has been identified as a halophilic "lactose-positive" marine *Vibrio*. Foodborne infection may result after consuming contaminated, raw, or undercooked seafood, particularly oysters and clams, with illness usually starting 16–48 hr after ingestion. The organism penetrates the intestinal tract and produces a primary septicemia. The illness usually begins with malaise, followed by chills, fever, and prostration. Vomiting and diarrhea are uncommon, but sometimes occur shortly after chills and fever. Hypotension (systolic blood pressure ≤80 mm Hg) is present in approximately 33% of the cases (Blake et al., 1979; Hollis et al., 1976). The fulminating infection progresses rapidly and may cause death in 40–60% of the patients (Oliver, 1985). Infection by *V. vulnificus* is *rare* in normal healthy people and is usually associated with certain risk factors, including liver disease, gastric disease, malignancy, hemochromatosis, and chronic renal insufficiency (Oliver, 1985; Blake et al., 1979). The most common vehicle for the organism is raw oysters.

V. vulnificus is widespread in the environment and has been isolated from estuarine waters of most U.S. coastal states (Oliver et al., 1982; 1983; Tilton and Ryan, 1987). Infection via the intestinal tract is most often associated with the consumption of raw oysters, but it is sometimes difficult to isolate from the molluscs. Oliver (1981a) demonstrated that antimicrobial factors lethal to *V. vulnificus* were released when oysters were homogenized for analysis. Kelly and Dinuzzo (1985) demonstrated that the presence of *V. vulnificus* in oysters was probably due to filtration of the bacterium from sea water rather than active multiplication in oysters.

The presence of *V. vulnificus* in water and shellfish is seasonal, being most prevalent when the water temperature is high (>20°C). Low salinity (0.5–1.6%) also favors the presence of *V. vulnificus* in seawater (Kelly, 1982). Some strains of *V. vulnificus* show bioluminescence, and these strains may also be pathogenic (Oliver et al., 1986). Environmental isolates are phenotypically indistinguishable from clinical isolates and produce virulence factors identical to those of clinical isolates (Tison and Kelly, 1986).

● ***V. mimicus.*** This species is biochemically similar to *V. cholerae*, with the exception that the strains are sucrose negative. In earlier publications, they were listed as *V. cholerae* of the Hieberg group 5; however, DNA homology studies demonstrated that many of the sucrose-negative strains were a separate species, and in 1981 the name *mimicus* was proposed because of the species' similarity to *V. cholerae* (Shandera et al., 1983; Colwell, 1984; Kaper et al., 1986). Both toxigenic and nontoxigenic strains have been isolated; however, food poisoning cases have been mostly from the nontoxigenic strains. Symptoms of the illness have included diarrhea in most cases, but approximately 67% of the cases included nausea, vomiting, and abdominal cramps. Diarrhea may be bloody and will last 1–6 days.

Raw oysters and boiled crawfish (crayfish) have been implicated as vehicles for the organism. *V. mimicus* is widely distributed in nature and can be found in fresh as well as brackish waters. It does show seasonal variation, being present in highest numbers in the warmer months (Bockemühl et al., 1986; Colwell, 1984).

● ***V. hollisae.*** This species (formerly EF 13) has been implicated in approximately 36 cases of food poisoning. Symptoms have included diarrhea and, in approximately half the cases, vomiting and fever. Seafood is implicated as the vehicle for *V. hollisae*, including raw oysters, clams, and shrimp (Morris et al., 1982).

The ecology of *V. hollisae* is not well understood because it grows poorly or fails to grow on thiosulfate citrate bile sucrose (TCBS) agar, the medium most often used in isolation of members of the genus *Vibrio*.

● ***V. furnissii.*** This species was previously classified as biovar II of *V. fluvialis*. *V. furnissii* has been implicated in foodborne illness (Brenner et al., 1983). It produces gas from glucose, an unusual characteristic among *Vibrio* species. Symptoms of illness include diarrhea, abdominal cramps, and sometimes nausea and vomiting.

● **Effect of Processing on Survival.** Members of the genus *Vibrio* are sensitive to many of the methods used to process food. All are relatively sensitive to heat, acid, radiation, and subfreezing temperatures. Shultz et al. (1984) observed that *V. cholerae* was heat sensitive, having a D value of 8.15 min at 49°C, 2.65 min at 60°C, and only 0.30 min at 71°C in crabmeat homogenate. Boutin et al. (1982) showed that preparation of oysters by common recipes effectively eliminates 10^5 *V. cholerae* 01/g of naturally contaminated oysters. However, Blake et al. (1980) observed that crabs that had been inoculated by placing them in seawater containing 10^4 *V. cholerae* O1 cells/mL and cooked by boiling for <8 min or by steaming for <25 min at atmospheric pressure contain viable *V. cholerae* cells. Of course, the size of the crab affects heat penetration. Himelbloom et al. (1983) observed that the internal temperature of a large crab (340 g) only reached 50°C after 8 min in boiling water. The above data of Shultz et al. (1984) suggest that *V. cholerae* would survive at this temperature.

V. parahaemolyticus is more heat sensitive than *V. cholerae*. Delmore and Crisley (1979) observed D values for *V. parahaemolyticus* in clam homogenate of 0.70 min at 49°C, 0.54 min at 51°C, 0.31 min at 53°C, and 0.24 min at 55°C. This study shows that the organism is killed by a relatively mild heating process. Supporting these findings is the work of Goldmintz et al. (1974), who demonstrated that steaming crabs for 5 and 15 min (internal temperature 88°C and 95°C, respectively) reduced *V. parahaemolyticus* populations by 6 log cycles. Hackney et al. (1980) observed that the commercial practice of heat shocking of oysters to facilitate opening reduced counts of all vibrios to nondetectable levels, suggesting that most members of the genus *Vibrio* would be killed by cooking. However, it should be noted that steaming of shellfish to facilitate opening usually does not provide enough heat to kill vibrios or other pathogens.

Kilgen et al. (1987) demonstrated that radiation levels of 100,000 rads was lethal to *V. cholerae*, *V. parahaemolyticus*, and *V. vulnificus* in live oysters. *V. cholerae* were slightly more resistant than either *V. parahaemolyticus* or *V. vulnificus*. The oysters were still viable up to a level of 250,000 rads. It is suspected that other *Vibrio* species are similarly sensitive, which suggests that radurization will render seafood safe from vibrios.

Many of the vibrios are somewhat sensitive to subfreezing temperatures. Vanderzant and Nickelson reported a 2-log reduction in counts of *V. parahaemolyticus* after 8 days of storage at −18°C. Thompson and Thacker (1973) observed that oysters held at −20°C for more than 2 weeks seldom contained viable *V. parahaemolyticus* cells. *V. vulnificus* is also sensitive to freezing, and rapid die-off (6 logs in 40 days) is observed at −20°C (Oliver, 1981; Boutin et al., 1985). However, freezing cannot be relied upon as a method of eliminating vibrios. For example, Reily and Hackney (1985)

demonstrated that *V. cholerae* will survive freezing in seafood homogenate for more than 2 mo.

V. parahaemolyticus's minimum temperature for growth is 8°C, and it will survive at refrigeration temperatures. In shellstock oysters, *V. parahaemolyticus* was observed to survive for at least 3 weeks with little or no decrease in numbers, and it has been shown to grow slowly at 10°C in oyster homogenate (Johnson et al., 1973; Thompson and Thacker, 1973). Temperatures below 8°C will usually stop growth, but it has been observed that the organism can still survive (Matches et al., 1971). *V. cholerae* survives refrigeration temperatures very well, and it has been suggested that cold enrichment will enhance recovery by decreasing competing *Vibrio* species. *V. vulnificus* is sensitive to cold; Oliver (1981) and Boutin et al. (1985) observed rapid decreases in counts at refrigeration temperatures.

V. parahaemolyticus is sensitive to low pH. Vanderzant and Nickelson (1972) reported that no survivors could be recovered from shrimp homogenate at pH values of 4 or below and that a rapid drop in viable counts occurred at pH 5 within 15 min. Beuchat (1976) also observed sensitivity to acid at pH values of 4.4 or below.

Plesiomonas shigelloides

Plesiomonas shigelloides (formerly *Aeromonas shigelloides*) has been implicated in human gastroenteritis for 40 years (Miller and Koburger, 1985). Symptoms of the infection include diarrhea (94%), abdominal pain (74%), nausea (74%), chills (49%), fever (37%), headache (34%), and vomiting (33%) (Miller and Koburger, 1985). The onset of symptoms usually occurs 24–50 hr after ingestion of the food. Foods implicated as vehicles for *P. shigelloides* include cuttlefish salad, salt mackerel, raw oysters, and undercooked oysters. In the U.S., raw oysters are probably the most implicated food.

P. shigelloides is widespread in nature, being mostly associated with fresh surface water, but may also be found in seawater. It is more often isolated during the warmer months (Miller and Koburger, 1985). Most strains of *P. shigelloides* have a minimum growth temperature of 8°C, but at least one strain has been reported to grow at 0°C. The organism is sensitive to pH <4 and salt concentration >5% (Miller and Koburger, 1986).

Clostridium botulinum

Botulism is an intoxication caused by consuming food in which *Clostridium botulinum* has grown and produced toxin. The toxin acts on the peripheral nervous system and may result in paralysis and death. Human botulism is relatively rare; however, the control and prevention of botulism is one of the most important considerations in food processing. Besides the devastating effect on human health, history has shown repeatedly that an outbreak of botulism can cause severe, often ruinous economic problems for processors. When problems arise, a whole section of the food industry is often affected, in addition to the processor involved (Eklund, 1982; Eyles, 1986).

C. botulinum, the etiological agent of botulism, is divided into eight types—A, B, C_1, C_2, D, E, F, and G—based on serological differentiation of the neurotoxin (Sakaguchi, 1979). The types have been divided by Smith (1977) into four groups according to proteolytic activity. Groups I and II are the most important with respect to human botulism. Group I includes type A and proteolytic strains of types B and F. This group is strongly proteolytic and produces putrid, unpleasant odors. It produces highly heat-resistant spores and has a minimum growth temperature of about 10°C. Group II includes all type E and nonproteolytic strains of types B and F. Group II is neither proteolytic nor gelatinolytic, and cultures do not produce putrid odors in food. This group can grow at temperatures as low as 3.3°C, and the spores of members of this group are heat labile.

C. botulinum is widely distributed in soils, and all types may be isolated from the aquatic environment (Dolman, 1964). Type E is the type most frequently isolated from aquatic environments and is most often implicated in botulism associated with seafood products. The spores of type E are most often isolated from freshwater and marine sediments in temperate zones (Dolman, 1964).

Most outbreaks of botulism associated with fishery products have implicated semipreserved products, i.e., smoked, salted, or fermented products that are eaten without further cooking (Eklund, 1982; Lynt et al., 1982; Hobbs, 1976). Type E is inhibited by water activity <0.975 (5% NaCl) and pH <5.3 (Emodi and Lechowich, 1969). The spores are sensitive to heat. Decimal reduction times at 82.2°C range from 0.49 to 6.6 min, depending upon the heating medium and the strain (Lynt et al., 1977; Simunovic et al., 1985; Cockey and Tatro, 1974). The spores are most resistant in tuna packed in oil. For foods not packed in oil, a D value of 4.3 min at 82.2°C is usually considered the maximum. Z values range from 4.8 to 9.6°C (Simunovic et al., 1985). For comparison, other members of Group II produce slightly more heat-resistant spores, with D values for nonproteolytic type B ranging from 1.49 to 32.3 min at 82.2°C. The D values for nonproteolytic type F are similar to those for nonproteolytic type B.

Most of the heat processes applied to seafood during processing will destroy *C. botulinum* type E. Hot smoking at a temperature of 82.2°C for a minimum of 30 min is assumed sufficient to destroy 10^7 spores of type E (Cann and Tayler, 1979). Placing crabs in boiling water for 15 min will provide a process equivalent to 37.5 min for a large crab (340 g) and 319 min for very small crabs (120 g)—these F values were calculated by us from the heat penetration data of Himelbloom et al. (1983), using a Z value of 16. Steam cooking of crabs under pressure in a retort is even more effective. F_{180}^{16} values calculated from the heat curves of Dickerson and Berry (1976) show that steam cooking under pressure in a retort for 10 min provides a process equivalent to 40,435 min at 180°C for a 240-g crab and 27,785 min for a 300-g crab. Pasteurization of crabmeat to a temperature of 185°C for 1 min at the cold point in a 1-lb 401 × 301 can provides a process equivalent to at least 63.7 min at 82.2°C. If one uses the D value of 4.3 min at 82.2°C, then it is easy to calculate the large safety factor provided by these processes: 74 D–8.7 D for boiling; 9,401 D–6,462 D for steam retorting; and at least 14 D for pasteurization. A 12-D process is considered adequate in canning.

Other forms of preservation processes may not provide safety. Radurization will kill spoilage bacteria but not destroy spores or toxin of type E (Eklund, 1982). Modified-atmosphere storage coupled with temperature abuse may create unsafe conditions (Garcia et al., 1987; Genigeorgis, 1985). Post et al. (1985) used inoculated and uninoculated finfish fillets and demonstrated the formation of toxin population before or simultaneously with sensory rejection. Therefore, storage at a temperature <3.3°C is critical.

Seafood Generally Safe

Every commodity has microorganisms associated with it that might cause potential safety problems. It is important that scientists, processors, and consumers be aware of potential safety problems so that food poisoning can be prevented. Overall, seafoods have a good safety record, and even seafoods that are consumed raw are usually safe for the general public. Verba (1983) reviewed all the shellfish-borne diseases from 1900 to the present. Sewage-borne pathogens are by far the greatest hazard. Bacteria of marine origin accounted for only a small number of the cases. However, our present knowledge of *V. vulnificus* makes it important that people in high risk categories avoid raw shellfish.

References

Barker, W.H. 1974. *Vibrio parahaemolyticus* outbreaks in the United States. Lancet 1: 551.

Beuchat, L. 1976. Sensitivity of *Vibrio parahaemolyticus* to spices and organic acids. J. Food Sci. 41: 899.

Beuchat, L. 1977. Evaluation of enrichment broths for enumerating *Vibrio parahaemolyticus* in chilled and frozen crab meat. J. Food Protect. 40: 592.

Blake, P. 1980. Diseases of humans (other than cholera) caused by *Vibrios*. Ann. Rev. Microbiol. 34: 341.

Blake, P. 1987. Vibrios on the half shells: What the walrus and the carpenter didn't know. Ann. Intern. Med. 99: 558.

Blake, P., Merson, M., Weaver, R., Heublien, P., and Hollis, D. 1979. Disease caused by a marine vibrio: Clinical characteristics and

epidemiology. New Eng. J. Med. 300: 1.
Blake, P., Allegra, D.T., Snyder, J.D., Barrett, T.J., McFarland, L., Caraway, C.T., Feeley, J.C., Craig, J.P., Lee, J.V., Puhr, N.D., and Feldman, R.A. 1980. Cholera—A possible endemic focus in the United States. New Eng. J. Med. 302: 305.
Bockemühl, J., Roch, K., Wohler, B., Aleksia, S., and Wokatsch, R. 1986. Seasonal distribution of facultative enteropathogenic vibrios (*Vibrio cholerae, Vibrio mimicus, Vibrio parahaemolyticus*) in the freshwater of the Elbe river at Hamburg. J. Appl. Bacteriol. 60: 435.
Bode, R., Brayton, P., Colwell, R., Russo, F., and Bullock, W. 1986. A new vibrio species, *Vibrio cincinnatiensis*, causing meningitis: Successful treatment of an adult. Ann. Intern. Med. 104: 55.
Boutin, B., Reyes, A., Peeler, J., and Twedt, R. 1985. Effect of temperature and suspending vehicle on survival of *Vibrio parahaemolyticus* and *Vibrio vulnificus*. J. Food Protect. 48: 875.
Boutin, B., Bradshaw, J., and Stroup, W. 1982. Heat processing of oysters naturally contaminated with *Vibrio cholerae*. J. Food Protect. 45: 169.
Bradshaw, J., Francis, D., and Twedt, R. 1974. Survival of *Vibrio parahaemolyticus* in cooked seafood at refrigeration temperatures. Appl. Microbiol. 27: 657.
Brenner, D., Hickman-Brenner, F., and Lee, J. 1983. *Vibrio furnissii* (formerly aerogenic biogroup of *Vibrio fluvialis*) a new species isolated from human feces and the environment. J. Clin. Microbiol. 18: 816.
CDC. 1966a. Cholera in Louisiana—Update. Centers for Disease Control, Atlanta, Ga. Morbidity Mortality Weekly Rept. 35: 687.
CDC. 1986b. Toxigenic *Vibrio cholerae* 01 infection—Louisiana and Florida. Centers for Disease Control, Atlanta, Ga. Morbidity Mortality Weekly Rept. 35: 606.
Cockey, R. and Tatro, M. 1974. Survival studies with spores of *Clostridium botulinum* type E in pasteurized meat of the blue crab, *Callinectes sapidus*. Appl. Microbiol. 27: 629.
Coffey, J., Harris, R., Rutledge, M., Bradshaw, M., and Williams, T. 1986. *Vibrio damsela*: Another potentially virulent marine vibrio. J. Infect. Dis. 153: 800.
Colwell, R. 1984. "Vibrios in the Environment." John Wiley & Sons, Inc., New York.
Colwell, R. and Kaper, J. 1978. *Vibrio cholerae, Vibrio parahaemolyticus* and other vibrios: Occurrence and distribution in Chesapeake Bay. Science 198: 394.
Colwell, R., Brayton, P., Grimes, D., Roszak, S., Huq, S., and Palmer, L. 1985. Viable but non-culturable *Vibrio cholerae* and related pathogens in the environment: Implications for the release of genetically engineered microorganisms. Biotechnol. 3: 817.
Cann, D.C. and Taylor, L.Y. 1979. The control of the botulism hazard in hot-smoked trout and mackerel. J. Food Technol. 14: 123.
Delmore, R. and Crisley, P. 1979. Thermal resistance of *Vibrio parahaemolyticus* in clam homogenate. J. Food Sci. 41: 899.
Desmarchellier, P. 1984. Significance of *Vibrio* spp. in foods. Food Technol. Australia 36: 220.
Dicharry, A. 1983. An improved methodology for isolation of Kanagawa positive *Vibrio parahaemolyticus*. M.S. thesis, Louisiana State Univ., Baton Rouge.
Dickerson, R. and Berry, M. 1976. Heating curves during commercial cooking of the blue crab. J. Milk Food Technol. 39: 258.
Dolman, C. 1964. Botulism as a world problem. In "Botulism," ed. K. Lewis and E. Cassel. Pub. No. 9999 FPI, p. 5. Pub. Health Serv., U.S. Dept. of Health, Educ. and Welfare, Cincinnati, Ohio.
Eklund, M.W. 1982. Significance of *Clostridium botulinum* in fishery products preserved short of sterilization. Food Technol. 36(12): 107.
Emodi, A. and Lechowich, R. 1969. Low temperature growth of type E *Clostridium botulinum* spores. 1. Effect of sodium chloride and pH. J. Food Sci. 34: 78.
Eyles, M. 1986. Microbiological hazards associated with fishery products. CSIRO Food Res. Quart. 46: 8.
Fujino, T., Sakaguchi, G., Sakazaki, R., and Takeda, Y. 1974. International symposium on *Vibrio parahaemolyticus*. Saikon Pub. Co., Tokyo, Japan.
Garcia, G., Genigeorgis, C., and Lindroth, S. 1987. Risk of growth and toxin production by *Clostridium botulinum* non-proteolytic types B, E, and F in salmon fillets stored under modified atmospheres at low and abused temperatures. J. Food Protect. 50: 330.
Genigeorgis, C. 1985. Microbiological and safety implications of the use of modified atmospheres to extend the storage life of fresh meat and fish. Intl. J. Food Microbiol. 1: 237.
Goldmintz, D., Simpson, R., and Dubrow, P. 1974. Effect of temperature on *Vibrio parahaemolyticus* in artificially contaminated seafoods. Dev. Ind. Microbiol. 15: 288.
Hackney, C.R., Ray, B., and Speck, M.L. 1980. Incidence of *Vibrio parahaemolyticus* in and the microbiology quality of seafoods in North Carolina. J. Food Protect. 43: 769.
Hackney, C., Kleeman, E., Ray, B., and Speck, M. 1981. Adherence as a method for differentiating virulent and avirulent strains of *Vibrio parahaemolyticus*. Appl. Environ. Microbiol. 40: 652.
Himelbloom, B.H., Rutledge, J.E., and Biede, S.L. 1983. Color changes in blue crabs (*Callinectes sapidus*) during cooking. J. Food Sci. 48: 652.
Hobbs, G. 1976. *Clostridium botulinum* and its importance in fishery products. Adv. Food Res. 22: 135.
Hollis, D., Weaver, R., Baker, C., and Thornsberry, C. 1976. Halophilic *Vibrio* species isolated from blood cultures. J. Clin. Microbiol. 3: 425.
Holmgien, J. 1981. Actions of cholera toxin and the prevention and treatment of cholera. Nature 292: 413.
Johnson, W., Salinger, A., and King, W. 1973. Survival of *Vibrio parahaemolyticus* in oyster shellstock at two different storage temperatures. Appl. Microbiol. 26: 122.
Kaneko, T. and Colwell, R. 1978. The annual cycle of *Vibrio parahaemolyticus* in Chesapeake Bay. Microbial Ecol. 4: 135.
Kaper, J., Nataro, J., Roberts, N., Seibeling, R., and Bradford, H. 1986. Molecular epidemiology of non-01 *Vibrio cholerae* and *Vibrio mimicus* in U.S. Gulf coast regions. J. Clin. Microbiol. 23: 852.
Kelly, M. 1982. Effect of temperature and salinity on *Vibrio* (*Beneckea*) *vulnificus* occurrence in Gulf coast environment. Appl. Environ. Microbiol. 44: 820.
Kelly, M. and Dinuzzo, A. 1985. Update and clearance of *Vibrio vulnificus* from Gulf coast oysters (*Crassostrea virginica*). Appl. Environ. Microbiol. 50: 1548.
Kilgen, M., Cole, M., and Grodner, R. 1987. Control of indicator and pathogenic bacteria in Louisiana shellstock oysters by ionizing radiation. Abstract of paper presented at 1987 Ann. Meet., Inst. of Food Technologists, Las Vegas, Nev., June 16–19.
Kolvin, J. and Roberts, D. 1982. Studies on the growth of *Vibrio cholerae* biotype El Tor and biotype classical in foods. J. Hyg. Camb. 89:243.
Levine, M. 1981. Cholera in Louisiana: Old problem, new light. New Eng. J. Med. 302: 345.
Lynt, R.K., Solomon, H., Lilli, T., and Kautter, D. 1977. Thermal

death times of *Clostridium botulinum* type E in meat of the blue crab. J. Food Sci. 42: 1022.
Lynt, R.K., Kautter, D., and Solomon, H. 1982. Differences and similarities among proteolytic and nonproteolytic strains of *Clostridium botulinum* A, B, E, and F: A review. J. Food Protect. 45: 466.
Madden, J., McCardell, B.A., and Read, R. 1982. *Vibrio cholerae* in shellfish from U.S. coastal waters. Food Technol. 36(3): 93.
Matches, J., Liston, J., and Daneault, L. 1971. Survival of *Vibrio parahaemolyticus* in fish homogenate during storage at low temperatures. Appl. Microbiol. 21: 951.
Miller, M. and Koburger, S. 1985. *Plesiomonas shigelloides:* An opportunistic food and waterborne pathogen. J. Food Protect. 48: 449.
Miller, M. and Koburger, J. 1986. Tolerance of *Plesiomonas shigelloides* to pH, sodium chloride and temperature. J. Food Protect. 49: 877.
Morris, J. and Black, R. 1985. Cholera and other vibrioses in the United States. New Eng. J. Med. 312: 344.
Morris, J., Wilson, R., Davis, B., Wachsmuth, I., Biddle, C., Wathen, H., Pollard, R., and Blake, P. 1982. Non-O Group 1 *Vibrio cholerae* gastroenteritis in the United States; Clinical, epidemiological, and laboratory aspects of sporadic cases. Ann. Intern. Med. 94: 656.
Morris J., Wilson, R., Hollis, D., Weaver, R., Miller, H., Tacket, C., Hickman, F., and Blake, P. 1982. Illness caused by *Vibrio damsela* and *V. hollisae*. Lancet 2: 1294.
Oliver, J. 1981a. Lethal cold stress of *Vibrio vulnificus* in oysters. Appl. Environ. Microbiol. 40: 710.
Oliver, J. 1981b. The pathogenic and ecology of *Vibrio vulnificus*. Marine Technol. Soc. J. 15: 45.
Oliver, J. 1985. Vibrio: An increasingly troublesome genus. Diagn. Med. 1.
Oliver J., Warner, R., and Cleland, D. 1982. Distribution and ecology of *Vibrio vulnificus* and other lactose fermenting vibrios in coastal waters of the Southeastern United States. Appl. Environ. Microbiol. 44: 1404.
Oliver, J., Warner, R., and Cleland, D. 1983. Distribution of *Vibrio vulnificus* and other lactose fermenting vibrios in the marine environment. Appl. Environ. Microbiol. 45: 985.
Oliver, J., Roberts, D., White, V., Dry, M., and Simpson, L. 1986. Bioluminescence in a strain of the human pathogenic bacterium *Vibrio vulnificus*. Appl. Environ. Microbiol. 52: 1209.
Paile, D., Hackney, C., Reily, L., Cole, M., and Kilgen, M. 1987. Seasonal variation in the fecal coliform population of Louisiana oysters and its relationship to microbiological quality. J. Food Protect. 50: 545.
Post, L., Lee, D., Solberg, M., Furgano, D., Specchro, J., and Graham, C. 1985. Development of botulinal toxin and sensory deterioration during storage of vacuum and modified atmosphere packaged fish fillets. J. Food Sci. 50: 990.
Ray, B., Hawkins, S., and Hackney, C. 1978. Method for detection of injured *Vibrio parahaemolyticus* in seafoods. Appl. Environ. Microbiol. 35: 1121.
Reily, L. and Hackney, C. 1985. Survival of *Vibrio cholerae* during cold storage in artificially contaminated seafoods. J. Food Sci. 50: 838.
Sakaguchi, G. 1979. Botuliam. In "Foodborne Infection and Intoxication," ed. H. Rieman and F. Bryon, p. 389. Academic Press, Inc., New York.
Sakazaki, R. 1979. Vibrio infections. In "Foodborne Infection and Intoxication," ed. H. Rieman and F. Bryon. Academic Press, Inc., New York.
Schwarz, J. and Colwell, R. 1974. Effect of hydrostatic pressure on growth and viability of *Vibrio parahaemolyticus*. Appl. Microbiol. 28: 977.
Shandera, W., Johnston, J., Davis, B., and Blake, P. 1983. Disease from infection with *Vibrio mimicus*, a newly recognized *Vibrio* species. Ann. Intern. Med. 99: 169.
Shultz, L., Rutledge, J., Grudner, R., and Biede, S. 1984. Determination of the thermal death time of *Vibrio cholerae* in blue crabs (*Callinectes sapidus*). J. Food Protect. 47: 4.
Simunovic, J., Oblinger, J., and Adams, J. 1985. Potential for growth of nonproteolytic types of *Clostridium botulinum* in pasteurized meat products. A review. J. Food Protect. 48: 265.
Smith, L. 1977. "Botuliam: The organism, its toxins, the disease." Charles C. Thomas, Springfield, Ill.
Speck, M.L. 1985. "Compendium of Methods for the Microbiological Examination of Foods." Am. Public Health Assn., Washington, D.C.
Spite, G., Brown, D., and Twedt, R. 1978. Isolation of one enteropathogenic, Kanagawa-positive strain of *Vibrio parahaemolyticus* from seafood implicated in acute gastroenteritis. Appl. Environ. Microbiol. 35: 1226.
Thompson, W. and Thacker, C. 1973. Effect of temperature on *Vibrio parahaemolyticus* in oysters at refrigerator or deep freeze temperatures. J. Inst. Can. Sci. Technol. Aliment. 6: 156.
Thompson, C.A. and Vanderzant, C. 1976a. Relationship of *Vibrio parahaemolyticus* in oysters, water and sediment and bacteriological and environmental indices. J. Food Sci. 41: 117.
Thompson, C. and Vanderzant, C. 1976b. Serological and hemolytic characteristics of *Vibrio parahaemolyticus* from marine sources. J. Food Sci. 41: 204.
Tilton, R. and Ryan, R. 1987. Clinical and ecological characteristics of *Vibrio vulnificus* in the northeastern United States. Diagn. Microbiol. Infect. Dis. 6: 109.
Tison, D. and Kelly, M. 1986. Virulence of *Vibrio vulnificus* strains from marine environments. Appl. Environ. Microbiol. 51: 1004.
Vanderzant, C. and Nickelson, R. 1972. Survival of *Vibrio parahaemolyticus* in shrimp tissue under various environmental conditions. Appl. Microbiol. 23: 34.
Verba, J. 1983. Shellfish borne disease outbreaks. Dept. of Health and Human Services, Shellfish Sanitation Branch, Northeast Tech. Services Unit, Davisville, R.I.
Xu, S., Roberts, N., Singleton, F., Attwell, R., Grimes, D., and Colwell, R. 1982. Survival and viability of nonculturable *Escherichia coli* and *Vibrio cholerae* in the estuarine and marine environment. Microb. Ecol. 8: 313.

Based on a paper presented during the IFT Food Microbiology Division/Seafood Products Technology Group program, "Microbiology of Marine Food Products," at the Annual Meeting of the Institute of Food Technologists, Las Vegas, Nev., June 16–19, 1987.

The authors acknowledge the help of Dr. Paul Blake of the Centers for Disease Control for providing information for this review.

—Edited by Neil H. Mermelstein, Senior Associate Editor